IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

IN RE:	)
	) No. 04-10981-PBS
NEURONTIN MARKETING, SALES PRACTICES, AND PRODUCTS LIABILITY LITIGATION	) MDL No. 1629
This document relates to: KAISER FOUNDATION HEALTH PLAN, et al, Plaintiffs	
-V-	)No. 04-10739-PBS
	)Pages 1 - 158
PFIZER, INC., et al, Defendants	

JURY TRIAL - DAY SIXTEEN

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts
March 15, 2010, 8:54 a.m.

LEE A. MARZILLI and DEBRA M. JOYCE
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 7200
Boston, MA 02210
(617)345-6787

A P P E A R A N C E S

FOR THE PLAINTIFFS:

THOMAS M. GREENE, ESQ. and ILYAS J. RONA, ESQ., Greene, LLP, 33 Broad Street, 5th Floor, Boston, Massachusetts, 02109.

THOMAS M. SOBOL, ESQ. and KRISTEN JOHNSON PARKER, ESQ., Hagens Berman Sobol Shapiro, LLP, 55 Cambridge Parkway, Suite 301, Cambridge, Massachusetts, 02142.

LINDA P. NUSSBAUM, ESQ., Kaplan Fox & Kilsheimer, LLP, 850 Third Avenue, New York, New York, 10022.

DON BARRETT, ESQ., Barrett Law Office, 404 Court Square North, P.O. Box 987, Lexington, Mississippi, 39095.

BARRY HIMMELSTEIN, ESQ., Lieff Cabraser Heimann & Bernstein, Embarcadero Center West, 275 Battery Street, San Francisco, California, 94111-3339.

FOR THE DEFENDANTS:

KATHERINE ARMSTRONG, ESQ., MARK S. CHEFFO, ESQ., and THOMAS E. FOX, ESQ., Skadden Arps Slate Meagher & Flom, LLP, Four Times Square, New York, New York, 10036.

RAOUL D. KENNEDY, ESQ., Skadden Arps Slate Meaher & Flom, LLP, Four Embarcadero Center, San Francisco, California, 94111.

JAMES E. HOOPER, ESQ. and ANDREW H. MYERS, ESQ., Wheeler Trigg Kennedy, LLP, 1801 California Street, Suite 3600, Denver, Colorado, 80202.

I N D E X

P R O C E E D I N G S

THE COURT: As I know you've heard, we have a problem. One of the jurors called in sick. What do you want to do?

MR. SOBOL: We'd like to continue again tomorrow, your Honor, defer today.

MR. CHEFFO: Well, I think, as your Honor knows, we have Dr. Gibbons here today, and we had made it clear throughout that this was his day. So I guess our proposal -- we're not pleased as your Honor, I'm sure the plaintiffs even, about dismissing jurors, so I see perhaps maybe two options, one pragmatic and doable. One is to dismiss the juror, which is certainly not the best option. The other option would be, why don't we have Dr. Gibbons testify today, and we can have the juror read the transcript.

THE COURT: Would that be acceptable?

MR. SOBOL: No.

MR. CHEFFO: I mean, I don't understand that. We basically said, your Honor, that -- you know, we've told them about this. They initially --

THE COURT: You have some scheduling problems with Mr. --

MR. CHEFFO: And tomorrow we have -- you know, again, I'm not casting blame at this point, but we were initially told they would be done last Monday, then Tuesday, then Wednesday, then Thursday, then Friday, and every day we've --

THE COURT: I'm inclined to dismiss the juror. Otherwise he's going to lose this witness. We'd still have seven.

MS. NUSSBAUM: Can we have a minute to talk, your Honor?

THE COURT: I'm either going to dismiss, or we're going to have to agree -- it's civil -- on having her read the testimony.

MS. NUSSBAUM: Can we have one minute to discuss that?

THE COURT: Yes.

(Pause.)

MS. NUSSBAUM: Thank you, your Honor.

THE COURT: What do you want to do?

MS. NUSSBAUM: We'll agree that she can read the transcript.

THE COURT: Okay. My basic view is, if you can agree to waive your Miranda rights and Speedy Trial, you can agree to waive anything. So you waive?

MS. NUSSBAUM: Yes, your Honor.

THE COURT: You?

MR. CHEFFO: Yes, your Honor.

THE COURT: All right, so the other issue is that another juror is running late because of the weather, so we'll just have to adjust for that. As far as the transcript goes -- well, I'll back up. Should we start with Mr. Gibbons,

Professor Gibbons, Dr. Gibbons?

MR. CHEFFO: Probably all three. All three of those, your Honor, I think would probably be fine.

THE COURT: Should we start with him?

MR. CHEFFO: That was our plan. As you recall, we --

THE COURT: We have a little bit of a deposition left.

MR. CHEFFO: We had a little bit of a deposition. It will probably take five minutes. Last night they were supposed to give another thirty-minute deposition. They told us last evening at about 8:00 o'clock that they're now not going to use the thirty minutes.

THE COURT: All right, that's fine. So good. Are you going to rest, short of the documents?

MR. SOBOL: Yes. I mean, we'll talk about that formally on the record at the -- unless you want us to do it right now.

THE COURT: While we're waiting for this juror, let's do this. I mean, we're about to do this, right? You have nobody else and no other depositions, right?

MR. SOBOL: Right.

THE COURT: You have what, ten minutes of a deposition left?

MR. CHEFFO: Probably less. I'm sorry.

MR. SOBOL: Thank you. We have to finish the Glanzman deposition, number one. Number two, there are two books,

Book 2 and Book 3, that the Court has sub judice.

Number three, there were three exhibits during the direct examination of the Kaiser witnesses that were admitted only as to certain pages, but we want to make sure that the entirety of the documents go in. Those are Exhibits --

THE COURT: Can we just do this one by one?

MR. SOBOL: Sure.

THE COURT: So I read the lengthy memo over the weekend, since there was nothing else to do on such a very rainy weekend. It was either that or Wolf Hall for my book group. So I did read your memo. He basically pulled in -- I didn't go check one by one against the documents -- he says, every document into his claims of enterprise. So unless you say that there's something that he hasn't referenced or is inappropriately referenced, I'd be inclined to allow in the documents.

MR. CHEFFO: Well, I mean, I guess, to the extent that, you know, I didn't find every single document, that wasn't necessarily our objection. If they say that they're referencing them, they're relying on them, even though we have other objections to the entire enterprise, you know, we think that it would be prejudicial. It's a document dump. You know, I think your Honor had said at the beginning of the trial that they need to authenticate. And just so we're clear, these wouldn't have all been documents, I think your Honor

recognized, just if you had Lloyd Knapp on the stand, you would have just been able to go, like -- you wouldn't have allowed that in because he wouldn't have seen the vast majority of those. There's no proffer of that. And essentially, again, you know, our position has been that they've had, you know, years --

THE COURT: Excuse me. But as I understand it, though, they are all authenticate and business records, and it's a 403 objection on a document dump theory. And that's why I forced them to write the memo, to link it in. Now, I have to admit I didn't sit and correlate every page of every document with every quote. I'm assuming there might be parts that you'd move to strike or sanitize or whatever, but --

MR. CHEFFO: I mean, that's the problem, your Honor. You know, again, this has been our position all along. Let's put aside authenticity and business record, okay? The real issue here is that I think your Honor has said, you know, appropriately a few times, one is, you're not going to allow document dumps. Two, certainly if you can't read the document, it's absolutely clear -- that was the second position -- they don't come in. So, you know, now we're going to have a situation where we're going to hear about these documents for the first time, your Honor, you know when? In closing argument. That's what they're going to do. We're not going to have a chance to even respond to --

THE COURT: That's their problem actually.

MR. CHEFFO: But it's our problem too, I mean, because what I suspect they're planning on doing is taking this entire binder which no one's ever heard of, and they're going to tell a different story to the jury in closing argument than any of us have heard in this entire trial.

THE COURT: Well, that's not accurate either because these depositions have been talking about Cline Davis and MAC, so essentially as I see it, these documents document that relationship, so it's not a complete -- well, it's not a surprise at all. But let just say, I'm going to allow it in, short of your moving to strike certain sections of them. I mean, I haven't gone through all the documents. Some of them were quite thick, and if there's only just one snippet of a quote from it, it may be inappropriate to put everything in. I don't know, and it would be subject to your moving to strike sections of them. You know, in other words, if there's a three-page e-mail chain and they've only quoted from part of it, if you wanted to, I suppose I could strike the rest of it. But short of sanitizing them, I'm going to allow them in, subject to somebody in your team telling me something wasn't referenced, because they put quotes from each one of them in the footnotes is what they did, which seemed pertinent. That's what I did read for, so --

MR. CHEFFO: We will go through them, your Honor.

The other thing that I would ask then is, pursuant to Rule 106, in case your Honor had ruled that way, we prepared a binder. Under the completeness rule, we basically think that if those are going to come in, that these need to also be in the record.

THE COURT: Have you shown --

MR. CHEFFO: Yes.

THE COURT: That seems fair, if they're authenticate and they're business records and they're tied into that. So you'd have to explain it to me why they are. That's what I forced them to do essentially is give me the quote from every document that proves up what you're talking about, and if you do it for me, what's fair for them is fair for you.

MR. CHEFFO: Okay, your Honor.

THE COURT: And also I allowed under 1006, the summary rule, each one of you to just give a list of the documents that you're submitting that way so that they can have that sense of it, but not the quotes. But I'm allowing stickies, that's how I'm resolving this, so that each side will go right to the area that you think is relevant on both sides.

MR. CHEFFO: Okay, and we have that message. We haven't done this yet, but I fear we're going to wind up with more Post-Its on these documents than anyone has ever seen in the universe, but we'll find that out in a few minutes.

THE COURT: If it's ridiculous, then I'll --

MR. CHEFFO: I just think that that's what's going to happen when you have these documents that no one's testified to, they're going to put them in, everybody's going to have --

THE COURT: They for the most part only have like one quote per document.

MR. CHEFFO: If we're going to sanitize the rest of the documents, that will make things a lot easier, if that's all they're going to put them in for.

THE COURT: If we want to go through that. Either that or we'll just put a sticky next to the quote that you're relying on for both sides.

In any event, there we are. What's the next one?

MR. SOBOL: Before we move away from that, your Honor, the defendants did give me their list this morning, so we will go through it, but I just haven't had an opportunity to react to it. We do have to finish the Glanzman deposition. And then, third, there were three exhibits admitted during the testimony of Kaiser witnesses in which I think the record might indicate that only the particular page that was being discussed at that particular time was admitted, but we think that the entirety of these documents ought to go in. Those are Exhibits --

THE COURT: There are only what? Say it again.

MR. SOBOL: During the testimony there was an objection that said, "Objection unless it's just to the page,"

and so during the testimony of the Kaiser witness, we fear that only that page of the document has been admitted in evidence. I'll give as an example --

THE COURT: Have you two talked about this? Why don't you talk to them about it.

MR. CHEFFO: We haven't talked yet about it. I don't even know what these documents are, frankly.

THE COURT: Why don't you talk about it and then --

MS. NUSSBAUM: This was with the first witness, your Honor. At that time -- this was the very first witness -- you said, rather than having side bars on documents, you know, it would be subject to later on. After that, the Court started letting in whole documents, every document came in with every witness. This was just with the first witness, when we started putting in documents, there were objections.

THE COURT: Why don't you just confer.

MS. NUSSBAUM: We'll confer. We'll tell them which documents --

THE COURT: It's not going to make a difference for a directed verdict issue.

MS. NUSSBAUM: Okay.

MR. SOBOL: No, I'm just trying to clean house. Then the final --

MS. NUSSBAUM: Just say the document numbers, and then they can get back to us.

THE COURT: There was one document we were waiting to hear whether or not you had received in discovery and didn't mark as an exhibit, the "snake oil" exhibit.

MR. SOBOL: Yes, the Wahlberg document -- we submitted something to you, your Honor -- was not produced to us during discovery, which is why it wasn't on our exhibit list. Apparently it was produced to the personal injury claimants by Skadden earlier this year, and we, the plaintiffs in this case, found out about it less than a week ago.

THE COURT: I understand, but did you receive it in discovery? You've checked?

MR. SOBOL: Yes, we checked, and we did not.

MR. CHEFFO: We filed, and I think I handed it up this morning, your Honor, filed ECF. I mean, I can just tell you briefly. The issue there, there's separate issues with respect to the personal injury cases, that this was after there was a motion made, and a ruling both by Judge Sorokin and the parties agreeing, we produced some documents. The real issue here, your Honor, is that this is a document that predates the merger, okay, so they're trying to use it as a business record or a statement by a party, but at the time, this document is a 1999 document by a -- who was a competitor of --

THE COURT: By Pfizer, though.

MR. CHEFFO: But at the time they didn't own Warner-Lambert/Parke-Davis. But, your Honor, the issue is, if

someone's saying something, a party against interest, at this point there were comments like if Ford is commenting on GM --

THE COURT: It's just an admission. It doesn't have to be against interest. It's a statement of a party opponent.

MR. CHEFFO: But they weren't a party opponent at the time.

THE COURT: Of course not. Of course they weren't. The suit hadn't been -- no, I'm going to allow it in if it wasn't produced in discovery. I'm not faulting you. Now, maybe it didn't fall within the parameters of Leo Sorokin's discovery orders. I'm not imposing a sanction, but I've held them very strictly, actually, to what exhibits were on the list and what weren't, what wasn't, I think with one exception everyone agreed on was a predecessor document or something like that. So, I mean, if it wasn't produced, that's why it wasn't on the exhibit list, and it falls under the party admissions standard. So I'm allowing it in.

So now what else? What else is there now?

MS. NUSSBAUM: Just to clarify the record, all three exhibits where only pages were put in were in Mr. Carrejo's testimony. It was 250, 352, and 355, and we will confer with the defendants.

THE COURT: Yes, just confer, yes. But it won't be relevant to directed verdict issues, right?

MS. NUSSBAUM: Well, we should confer on a break and

hopefully resolve it today.

THE COURT: And then Glanzman finishes, and then you rest. So you'll come up. Have you filed your memo yet?

MR. CHEFFO: No. They haven't rested yet, so --

THE COURT: No, no, I know, but --

MR. CHEFFO: As soon as --

MR. SOBOL: Can we say it?

MR. CHEFFO: My turn now.

MR. SOBOL: We rest subject to finishing Glanzman. Thank you, your Honor.

MR. CHEFFO: And we move under Rule 50. We have -- you know, as soon as they finish that, people are standing by, your Honor, to file ECF, and we'll give you courtesy copies.

THE COURT: Just have them do it. What is the big deal? Just --

MR. CHEFFO: We could do it now. I mean, I thought it said under the rules you're not allowed to do it until they rest. Now they've rested, so --

THE COURT: Well, subject to Glanzman.

MR. CHEFFO: Subject to Glanzman, understood. And we're also understanding that, you know, there's no waiver here. I'm not required to --

THE COURT: How long is it?

MR. CHEFFO: We've moved on -- well, basically, as we talked about last week, there's about four or five separate

kind of pieces. So one is going to be on causation. One is going to be on statute of limitations. One is going to be on the injury. The other one is going to be on enterprise. Some of them are longer, some of them are a little bit shorter, but they're spelled out. So, in other words, both your Honor and counsel can respond individually as opposed to just some mammoth brief.

THE COURT: There are five separate briefs? How many pages does it come to?

MR. CHEFFO: I don't have the specifics, your Honor.

MR. SOBOL: Give us a guess.

THE COURT: A hundred pages?

MR. CHEFFO: No, no, no, less than 100 pages. I think the largest one is probably less than 20 pages, and then I think the statute of limitations is probably 12 pages. And we've tried not to be duplicative of repeating everything and trying to cross-reference where appropriate.

THE COURT: I don't know when I'll get a time to -- I'll take it on the plane with me, but --

MR. CHEFFO: We'll file them and have them for you this morning, your Honor. We can give you copies.

Now, here's the other thing. If I can hand these up, these are --

(Discussion between the Court and Clerk.)

THE COURT: Do you want to go see if that juror is

here. There's a lot of flooding on the area roadways, for example, Storrow Drive, so it may well be that --

MR. CHEFFO: Your Honor, we're mindful of the rule, the 24-hour rule. We may not need it for today, but when we heard that they were dropping the thirty minutes, we thought we may have some time that we don't want to leave your Honor or the court with any wasted time. So to the extent that we do have time today, we would ask that your Honor focus, if you would, on Chandler and Day because that would give us about a half hour if we're not going to get to them. Then tomorrow we expect that we may need some rulings, if your Honor would, with respect to these depositions.

These are -- just to put it in context, you'll remember there was a motion in limine with respect to which doctors can be read or not, and these are primarily Kaiser doctors, both on the issue of causation and efficacy. And then there were the two doctors that you allowed in which were the two class doctors where they had an opportunity. The others we have not designated.

THE COURT: And are they videos, or are they read-ins?

MR. CHEFFO: The Kaiser folks are all video. The class people for whatever reason are read. But the class people are -- one is a total of 19 minutes, the other is a total of 12 minutes, so they're not exceptionally long.

MS. NUSSBAUM: With respect to the class people, your

Honor, we would again renew our objection and ask that if the Court determines that they're going to allow that to be read, that the jury be given a limited instruction saying that these are not PMG physicians, the patients are not Kaiser members, and they are not part of the lawsuit.

THE COURT: So who are they?

MS. NUSSBAUM: Apparently they are --

THE COURT: Not apparently. I mean, who are they?

MS. NUSSBAUM: They are the physicians of consumer class representatives in the class action. Kaiser personally did not attend. We personally never thought that these depositions would in any way be used in our case with respect to Kaiser. These were class reps.

THE COURT: Yes, but their depositions were taken, right? Right, so it's under oath. I mean, I'm not saying they're party admissions. I'm just saying they're --

MR. GREENE: They were treating physicians of two of the class reps, your Honor.

THE COURT: Fine, so what's -- I mean, they're just doctors. Right, I'll say they weren't Kaiser doctors.

MS. NUSSBAUM: Okay.

THE COURT: I mean, they're just --

MR. CHEFFO: I think they say specifically who they are. They don't represent themselves as Kaiser doctors.

THE COURT: Yes, but it might be confusing.

MS. NUSSBAUM: We want it made clear to the jury that they're not PMG doctors.

THE COURT: Yes, okay.

MR. CHEFFO: We have no objection to that, your Honor. The only other -- I guess just two other --

(Discussion off the record between the Court and Clerk.)

MR. CHEFFO: Do you want to deal with some housekeeping things now, your Honor?

THE COURT: We're just waiting for the juror. Why not?

MR. CHEFFO: Last night we received three exhibits that they want to apparently use. Now they've kind of put them as Plaintiffs' Exhibit 478, but the bottom line is, these were documents that were produced previously, and this new designation was kind of made up. These were never on their exhibit list, so --

THE COURT: Were they not on the list?

MR. SOBOL: Well, yes and no. These are reliance materials of one of their experts, so these are materials that one of their experts says, "I relied upon." They even reference them in their declaration.

THE COURT: Which expert?

MR. SOBOL: Arrowsmith-Lowe.

MR. CHEFFO: They were not Dr. Gibbons' reliance

materials.

MR. SOBOL: No. They're Arrowsmith --

THE COURT: So what, you want to show it? You're not going to put them in through him; you're just going to ask about these?

MR. SOBOL: Yes, I'm going to ask him questions. And then when Arrowsmith-Lowe takes the stand, I'm going to introduce them in evidence, and I want to be able to have them marked that way.

THE COURT: And why can't he ask questions?

MR. CHEFFO: No, I mean, he can ask questions. I mean, he put them as Plaintiffs' Exhibit 476, which led me to believe he was going to try to admit them.

MR. SOBOL: Well, and I am, but not today, just through Arrowsmith-Lowe, and I'm going to use them as a chalk today.

THE COURT: So he's going to do it through --

MR. CHEFFO: He can't publish these, though, until they're admitted. I think that's the rule that we had.

THE COURT: Right, but he can ask about them.

MR. CHEFFO: He can ask questions about it. He just can't publish or introduce.

THE COURT: Right.

MR. CHEFFO: And then with respect to the last issue, and again, your Honor, it's pretty short, but if we do have

some time, I --

THE COURT: Although can I just say just for point of, so we're just not playing a game here, is that witness going to show up?

MR. CHEFFO: No, actually, we're not sure that she is. She may not show up.

MR. SOBOL: Oh, that's new.

MR. CHEFFO: I've told you that all along.

MR. SOBOL: No. Arrowsmith-Lowe is a possibility of today or tomorrow, so I might try to put them in through Gibbons then. We've been told she's going to be here.

MR. CHEFFO: She may not, your Honor.

THE COURT: Excuse me, excuse me. Both sides, if she shows up -- this is what I don't want, this gamesmanship. If she's going to show up, I will let him put it on the screens just so it will be clearer to the jury. If she's not going to show up, then we have another issue.

MR. CHEFFO: I'm not going to -- we're still figuring it all out, so I'm not going to represent to the Court that she's absolutely going to show up. She may not show up. So you should be guided by that --

THE COURT: Is there a problem with the -- why not put it on the screen if there's at least some chance she's going to come? I'm not saying introduce it. That's his problem, but --

MR. CHEFFO: Well, again, for the same reasons that

we've just been talking about that, you know, it's kind of unfair surprise, and, you know, what's good for the goose. I mean, we couldn't show anything --

THE COURT: Excuse me. When was this shown to you?

MR. CHEFFO: It was shown to us last night at 6:00 o'clock or so.

THE COURT: I don't know, that seems like gamesmanship because if in fact she's likely to show or fifty-fifty, I don't know, I don't have a problem. Is there any problem with it? Is it a business record? What is it?

MR. SOBOL: It's letters with the FDA, between Pfizer and the FDA regarding Neurontin, that their expert has as her reliance materials and which she refers to in her report.

THE COURT: Well, if it's --

MR. CHEFFO: If you're going to let him publish it, your Honor, then --

THE COURT: I'm going to let it be published but not introduced, and if she doesn't come, it doesn't get introduced.

(Discussion off the record between the Court and Clerk.)

THE COURT: She's not here yet.

MR. CHEFFO: This really I think is my last, subject to Mr. Sobol's, and, again, if we have a few minutes, your Honor, we did file a very short -- I think it's essentially a four-page brief in support of a motion to reconsider the ruling

with respect to Dr. Rothschild. Again, I think it says it better than I can, but --

THE COURT: It may be upstairs. I just walked in and came downstairs.

MR. CHEFFO: I have another copy. It's really very short. Again, I can tell you what it is. I think it --

THE CLERK: Is that what you gave me earlier, Mark?

MR. CHEFFO: I did. There was two issues. One was a brief which is now moot with respect to --

THE COURT: What's really going on here? Is Slaby not available to you?

MR. CHEFFO: No, we believe Slaby is available, but here's the problem, your Honor, that we have, is that Dr. Furberg was never designated by these folks, never. He was a class plaintiff expert, okay, so he was never on the list. We never -- you know, talk about surprise -- we never would have even assumed to depose him in connection with any of these cases.

THE COURT: Excuse me. That's a little unfair, in that these cases always ran in tandem, right?

MR. CHEFFO: But if that's true, then that supports what we're saying, so just give me one second. I agree with you in that regard, but they came and they put him on their witness list, Furberg, the Kaiser people, on November 23 for the first time, okay? We then designated Dr. Rothschild, and

what you said all along is, the witnesses should -- if they had a chance to depose them and its in their report, I'm not going to play formalistic games, that everyone's known about them. And those are rules that I'm really not quibbling with at this point, and I think we understand that. And our point here is -- maybe your Honor didn't recognize this -- Dr. Rothschild's report was provided to the plaintiffs on March, 2009, okay? So they had it for a full year, and our only position is, if you're going to allow these people to add Furberg on November, 2009, just by putting him on a witness list, then the person who is responding to him is Rothschild, and Rothschild --

THE COURT: But wasn't the theory that he was responding to Furberg? That was the theory.

MR. GREENE: This is exactly what it was, your Honor, and we gave up our right to depose him.

THE COURT: And I'm going to allow him to do whatever he wants with respect to responding to Furberg.

MR. CHEFFO: But he should not be limited to -- in other words, what I think your Honor, either intentionally or based on what was represented to you, has limited him to things that are -- there's things in his report that they were on notice of that he should be able to testify to.

THE COURT: I thought the deal was, he wasn't being deposed. The deal was, he was going to be -- that was the quid pro quo: You can add Furberg, and he can respond to

Furberg.

MR. CHEFFO: No, but they haven't even deposed Slaby. They haven't deposed any expert. So to basically say that all of a sudden --

MR. SOBOL: That's not true. We have.

MR. CHEFFO: Slaby?

MR. SOBOL: No, but we have deposed experts.

MR. CHEFFO: They deposed Dr. Keeley, okay, so this idea that --

THE COURT: I'll read it at this point, so --

MR. GREENE: Your Honor, may I just refresh your memory and Mr. Cheffo's because I'm not positive -- and forgive me, Mark -- I'm not sure if he was in the case at that point, but we identified and asked for permission to supplement Barkin's report and identified Dr. Furberg to address this very narrow issue of whether, based on the FDA '92-'93 statistical findings there, there was increased risk of depression. That was it. They came in with Rothschild. We didn't oppose it, and we gave up our right to depose Rothschild, and you allowed it. And Rothschild was allowed in just to respond to the narrow testimony, proposed testimony of Barkin and Furberg. He's gone way, way beyond that, and that was what the motion practice was on that issue.

THE COURT: But you have too restrictive a view of what that means. I mean, he can say that, you know, "In my

view, it doesn't have depressive side effects," and look at clinical studies to support that, I mean, if in fact he has them. So, I mean, I think they have taken too broad a view, which is simply by the fact Barkin says, "I incorporate my prior report or my prior opinion," you know, that somehow opens the floodgates. It doesn't. But you have too narrow or restrictive view about it. I mean, he can say, "And I've looked at the clinical studies, and it doesn't have depressive side effects, and in my clinical experience, I haven't seen that," right?

MR. GREENE: I think he can be limited to that issue, that issue of what Furberg and Barkin talk about, and that is whether Neurontin increases the depressive side effects. That's what they addressed, but not in her --

THE COURT: Let me put it this way: I am unlikely to reconsider my order, but I am not going to be as narrow as what you think it is. So it's, you know, "No, it doesn't increase depression. I have looked at the clinical studies," if so there be, "and I haven't seen any indications that there's depression coming out of gabapentin. And I've got a long clinical practice. I'm a doctor from McLean's," you know, the great, "and I haven't seen it." So I'm assuming that's what --

Now, what I'm not going to allow him to do is say it's an effective drug for bipolar because that's way beyond. You'll have to bring in Slaby for that if he's going to say it.

As I understand it, there is no evidence in Furberg or whatever that goes into general effectiveness for bipolar.

MR. GREENE: There isn't, there isn't. He was limited to that safety signal. That's all he addressed.

MR. CHEFFO: The only thing I would say, your Honor, is what you said, I think, what's good for the goose. I know your Honor uses "what's sauce for the goose." And I would just say, if you just take a look at the brief, the real issue here is what's in his report or not. So I think we're on the same page with respect to where you are, what he can testify, but I would just ask also that he not be limited. If it's in his report, it should be fair game. That's in the rules --

THE COURT: No. His report goes way, way beyond. And I didn't sit and micromanage, well, "yes" to Vieta and "no" to this. I'm not going to do that. I don't understand it well enough, and I didn't sit and read the very lengthy report that he wrote, so I didn't read the whole story. However, I have a general sense in my mind that Furberg and Barkin talked about the safety end, the depressive side effects or suicidal side effects. And they say, "Well, it's bad for that reason," and Rothschild can say, "That's crazy. I use it all the time. I don't see it, there are clinical trials that don't appropriately show it." I know Dr. Gibbons is going to talk about why gabapentin shows differently from some of the other antiepileptics. That's his big thing. And it will be for the

jury to swallow.

But let me just ask you all this: At some point I'm going to need to have time with you, right, on this directed verdicts issue?

MR. SOBOL: You had mentioned Friday afternoon, your Honor.

MR. CHEFFO: Friday for oral argument?

THE COURT: Yes, does that make some sense?

MR. CHEFFO: It makes perfect sense.

THE COURT: I'm starting to do the jury instructions, and one thing I'm struggling with a little bit, which you did not a bang-up job on, and unfortunately I think there aren't model ones, is on the California thing. I'm just having trouble with how I talk to a jury about it. Like, for example, there's case law that says there's strict liability. Well, that can't be true, I mean, for fraud? I mean, so at some point, maybe I'll just --

MR. CHEFFO: I was going to say, if you have questions on California law, Mr. Kennedy may be the one to --

THE COURT: Let me ask you point-blank: Are their model jury instructions for the unfair competition under California law?

MR. KENNEDY: There are not because it always gets tried to a judge.

THE COURT: I understand people think it's a good idea

to try and give it on an advisory basis. We're just sort of struggling as to how to talk about it to a jury.

MR. KENNEDY: I'm unaware of any advisory set of jury instructions on the issue.

THE COURT: So I'm struggling because case law says, well, in some contexts there's strict liability. Well, A, they're not going to understand what that means; and, B, it can't be true, at least for the fraudulent advertising piece of it. There has to be some scienter. So I'm just -- you put that in your jury instructions. And maybe like under the Mass. 93A, sometimes there's strict liability when there's a violation of an Attorney General regulation, but it's not always the case for other kinds of causes of action. So I'm sort of -- maybe your brief goes into the case law a little bit better on that. I don't know.

MR. CHEFFO: You know, I think that it does not specifically, your Honor, because I think, as we understand the law, is that your Honor has to have the jury go first on the jury issues. So our Rule 50, just so your Honor is clear, doesn't even cover the UCL claims because that's something that we assumed you wanted to hear, you know, everything and you're sitting as the trier of fact, but we --

THE COURT: I thought you didn't. I thought everyone wanted me to do an advisory on it.

MR. CHEFFO: We do, your Honor, and I think that makes

sense. I'm only saying for the Rule 50, but if you're -- we submitted our proposed jury instructions. If you have questions, we can take another stab at it.

THE COURT: Another thing for you all, we were struggling with RICO conspiracy. I'm trying to articulate to myself what the difference is between the C and the D in this context, and it makes no sense. In other cases I've had criminally, it does make sense.

MR. SOBOL: I can address that, your Honor.

THE COURT: Yes.

MR. SOBOL: So now that the plaintiff has rested and our evidence is in, we don't intend to go to the jury on the conspiracy claim, just the substantive RICO count. But just this can be a placeholder in here, I did want to address some Gibbons chalks before he goes on the stand.

MR. GREENE: Can we just finish up with Rothschild? This is a binder of the exhibits in the report, and I highlighted the report in yellow and red.

THE COURT: About what?

MR. GREENE: Where he's going beyond his --

THE COURT: Gibbons?

MR. GREENE: No, Rothschild.

THE COURT: Rothschild. For Gibbons, I mean, we've known about Dr. Gibbons for a long time now. I know exactly what he's going to say. You all know exactly what he's going

to say. He's been consistent.

MR. SOBOL: He's different in this case, your Honor.

THE COURT: What else? Everybody's fine?

MR. CHEFFO: I'm done, your Honor.

THE COURT: Good. I'm going to go upstairs and have a cup of coffee. No?

MR. SOBOL: I'm sorry. I just have a couple of objections to the Gibbons slides that the defendants sent to us last night. I don't have an extra copy of them. If you have one that we can give to the Court or maybe --

THE COURT: Is it just demonstratives?

MR. HOOPER: Demonstratives.

MR. SOBOL: My only objections are twofold: Number one, if there's something brand-new, a new calculation that was not in his report, I'm objecting to it, or a brand-new chalk that has calculations that he did not depict in his report.

THE COURT: Well, there are calculations and there are calculations. So like I did with you, if there are some simple percentages, that's fine. If it's complex, we're going to cut it out.

MR. SOBOL: Exactly, which is why I limited my objections to --

THE COURT: Can you two talk?

MR. HOOPER: It would be nice. I never heard of this until two seconds ago.

THE COURT: I know, but, you know, he probably just saw the graph. Why don't you talk and see if they're brand-new. You know, there was an issue that -- I'm not faulting anyone -- which really turned out to be a new calculation that you ended up having to change because Ms. Armstrong caught something. So why don't you just talk and see if there's a serious problem. Have you talked about this?

MR. SOBOL: No. Again, I got the slides, and we've been busy, so --

THE COURT: Yes, of course you've all been busy.

MR. HOOPER: Last night.

THE COURT: And plus you theoretically have a life, so --

MR. CHEFFO: Theoretically.

MR. SOBOL: And you're looking at it.

(Laughter.)

THE COURT: You were all at that St. Patrick's Day parade yesterday in South Boston. You were the people standing there, right, in the pouring rain?

So, anyway, let's do this. You talk. As soon as this juror gets here -- there is flooding throughout --

THE CLERK: She's here.

THE COURT: She is here. All right, let's go.

MR. SOBOL: Are we going to finish Glanzman now?

THE COURT: No. Let's go right to Gibbons and do

Glanzman later. Is that a problem, so you can get him out of here?

MR. SOBOL: Well, we might need to chat about this right now then.

THE COURT: Yes, do you want to talk for two minutes?

(Discussion off the record.)

MR. SOBOL: We have one dispute.

(Discussion at side bar off the record.)

THE CLERK: All rise for the jury.

(Jury enters the courtroom.)

THE COURT: Well, good morning. Once again, you've been delayed. I understand that one juror got caught in some of this horrific weather, and that's understandable.

The bigger problem is this: One of the jurors is sick, and we've been having a big debate about what to do about it, the options being sending you all home for the day, dismissing her. We decided against both of those, and what we're going to do here is, we're going to give her a transcript of what happened today so that she can get caught up. You've been in on this for a while. We hate to do that. She thinks she'll be better tomorrow. She says her whole family is down with something. So I think what we're going to do is go forward without her today. We will give her a transcript to read of whatever she missed.

The other issue is so that we can get -- we have only

a tiny amount left of Dr. Glanzman's deposition and the plaintiff will rest, but because we have the first of the defendants' witnesses here, we're just going to try and get him out of here, the weather is so horrible, get him home so that we can make sure we can finish him today. So we're going to start with him, but, remember, they haven't quite rested because what is it, ten or fifteen minutes left with Dr. Glanzman, something like that? And that will be part of it, and as well there are several documents they have introduced that you haven't seen yet but which they may save some oral argument on, but they'll offer those, and then I think we're going to get started on Dr. Gibbons.

MR. CHEFFO: Yes, your Honor.

THE COURT: And is he your only live witness today, and then you have otherwise depositions if we need time, is that it?

MR. CHEFFO: No, your Honor. We do have the depositions, but also Dr. Rothschild will be available.

THE COURT: Oh, he's coming in today?

MR. CHEFFO: Yes, your Honor.

THE COURT: Oh, all right, well, fine. So he's local. He's one of the local doctors, so we're not depending on travel.

Okay, go ahead.

MR. HOOPER: Your Honor, we call Dr. Robert Gibbons.

ROBERT GIBBONS

having been first duly sworn, was examined and testified as follows:

THE CLERK: Would you please state your name and spell it for the record.

THE WITNESS: Robert Gibbons, G-i-b-b-o-n-s.

THE COURT: I'm sure you're not catching. Can you hear? Pull it in. You can move it, as you may remember. All right, so let's try it again.

THE WITNESS: Robert Gibbons, G-i-b-b-o-n-s.

THE COURT: Perfect.

DIRECT EXAMINATION BY MR. HOOPER:

Q. All right, Dr. Gibbons, what is your profession?

A. I'm a professor of statistics.

Q. Before we get into your background, would you please describe your assignment in this case, what you're here to talk about.

A. I was asked to review the expert reports of Dr. Perry, Dr. Jewell, and Dr. McCrory, and comment on the analyses that were performed therein and verify those computations.

Q. Where are you employed?

A. University of Illinois at Chicago.

Q. In what capacity?

A. I'm the Director for the Center For Health Statistics. I'm a professor of biostatistics, statistics, math, computer

science, and psychiatry, kind of an odd mix.

Q. And in what fields of science did you earn your doctoral degree?

A. In statistics and in psychometric theory from the University of Chicago.

Q. Have you published peer-reviewed scientific papers in your field?

A. Yes, I have.

Q. Have you published books as well?

A. Yes, I have.

Q. How many peer-reviewed publications do you have in your field?

A. Over 200 peer-reviewed publications and five books.

Q. And you published a book on something called longitudinal data analysis?

A. Yes, I have.

Q. Does longitudinal data analysis have something to do with analyzing data from clinical trials?

A. Yes, it does.

Q. And is your book used in academic institutions to teach data analysis?

A. Yes. It's quite widely used. I believe there are fifteen universities currently that are using the book for routine classes in analysis of longitudinal and clustered data.

Q. Has your work through the years involved analysis of data

from studies of pharmaceutical products, medications?

A. Yes, it has.

Q. Dr. Gibbons, has your work in biostatistics resulted in recognition or awards from Harvard University, the American Statistical Association, agencies of the federal government like the National Institute of Mental Health and the Veterans' Administration?

A. Yes. They've all been very kind to me.

Q. And are you a member of the Institutes of Medicine of the National Academy of Sciences?

A. Yes, I am.

Q. Can anyone join the NAS? Is it something where you fill out the application, send in your dues, and get the membership card back?

A. No. It's a select group that has to be nominated by two members of the National Academy of Sciences based on the lifetime achievement in a particular area. Worldwide, I believe there are approximately a thousand members. There are a handful of statisticians that are members of the National Academy of Sciences. I'm one of them.

Q. Have you been asked to serve on advisory boards to the Food and Drug Administration?

A. Yes. I was a member of the Scientific Advisory Board that opined on the question of antidepressants, suicide in children. I've also recently been appointed and elected to the Safety

Science Board of the new Sentinel Network that oversees FDA's new approach to drug safety in the United States.

Q. Before we get into the details, could you please give the jury a brief summary of your major opinions in this case.

MR. SOBOL: Objection.

THE COURT: Overruled.

A. My opinions are, number one, that the data clearly support the effectiveness of Neurontin in neuropathic pain. The data do not support Dr. Perry's conclusion that Neurontin is ineffective. Second, based on my reanalysis of the data, the data do not support Dr. Jewell's unblinding hypothesis. And, finally, the data do not support Dr. McCrory's conclusion that Neurontin is ineffective for migraine headache pain.

Q. Before we get into the specific opinions, let's spend just a few minutes on some basic terms and concepts.

MR. HOOPER: Bring up Slide 6, please.

Q. When you say you analyze clinical data, Dr. Gibbons. What does that mean? What is clinical data?

THE COURT: What's up on the screen?

MR. HOOPER: I think he can explain. It will help answer the question.

MR. SOBOL: Objection.

THE COURT: Sustained.

MR. SOBOL: Can we take it off, please?

THE COURT: Yes.

Q. What is clinical data, Dr. Gibbons?
A. Clinical data in this case are unique, in that these are patient-reported outcomes. This is a patient's self-report of their physical well-being in terms of the amount of pain that they're experiencing. This is quite different than looking at cholesterol levels or blood pressure or heart rate measurements that are less of a subjective measurement and are not reported directly by the patient.
Q. Now, what is a PGIC scale?
A. PGIC is what we call a Likert type scale. It's a series of ordered categories, each one having a description in which a patient rates themselves in terms of, in this case, the change in their global impression of their pain.
Q. Are the scores that patients record on the scale, is that one form of clinical data?
A. Yes, it is.
Q. And are there other similar scales that record information passed from patient to doctor in the clinical trials about pain?
A. Yes. This is very characteristic of pain studies to rate pain on a kind of rating scale with categories that are ordered and are labeled to describe, for example, my pain is much worse, or my pain is much improved, or there is no change in my pain.
Q. Doctor, what does longitudinal analysis of clinical data

mean?

A. Longitudinal data are data that consist of repeated observations of the same people over time. The most important feature of longitudinal data and why they're collected routinely in randomized clinical trials is that not everybody makes it to the end of the study, and so we're confronted as statisticians and clinical researchers with the question of, what do we do with the patients that drop out from those studies? The longitudinal data allow us to obtain all available information from those subjects so that they can in fact be included in the analysis and not excluded. This helps to insure that the effects of randomization in these trials is maintained.

THE COURT: So longitudinal data is just from the dropouts or from everybody?

THE WITNESS: It's from everybody.

Q. And is this the type of analysis, longitudinal data analysis, that your book is about?

A. Yes, it is.

MR. HOOPER: Slide 9, please.

THE COURT: So do you follow people after they've dropped out or just while they were in it?

THE WITNESS: You follow people while they're in the study. So if a patient, say, in an eight-week study had data through week seven, we're able to use the data through week

seven, even though they dropped out at the end of the study, to make use of the available data from those subjects to tell us something about --

THE COURT: While they're still in the study?

THE WITNESS: While they're still in the study.

Q. Doctor, can you explain for the jury the difference between clinical data in its original state, the score sheets from doctors and patients, and the data information that comes in things like study reports and publications.

A. The original clinical data maintain the responses for every individual that was randomized in the study and maintain the individual measurements at each measurement occasion. It is the complete record of the experience of the patient in the clinical trial.

The study reports present summary statistics, averages, proportions, standard deviations, that describe the experiences of the group of subjects to which received a similar treatment; for example, Neurontin or placebo.

And then, finally, the publications are the reports of those summary statistics and analyses that made it into the scientific literature.

So you can see that there are three levels of organization, three levels of data. Things like meta-analysis are typically applied at the highest level in terms of the publications, sometimes also based on study reports. The

original data can be used for reanalysis.

Q. In certain of your analyses in this case, were you able to use original clinical data?

A. Yes. I believe it's very important to go back to the original clinical data. It allows us to understand which patients made it to the end of the study, which patients did not, how those patients were treated, and allows for a much richer way of synthesizing the information from study to study. So I was able to go back to the original data and perform these analyses. I believe I'm the only one who's actually looked at the original data.

MR. HOOPER: Slide 10, please.

Q. Dr. Gibbons, what is a parallel group study design?

A. Parallel group study is a study in which patients are randomized to either a treated, an active treatment like Neurontin, or a control condition, or another treatment like placebo or a different kind of, say, antiepileptic drug. The distinguishing feature is that these are independent groups of people who are randomized either to Treatment A or Treatment B, Treatment A or a placebo-controlled group.

Q. Is this a common design for clinical trial?

A. This is the most common clinical trial design.

THE COURT: Are you describing what we've been calling the double-blinded random controlled trial?

THE WITNESS: You can have a double-blinded control

that involves a crossover as well, so it could be the same people being treated in both cases. They still are double-blind. So the distinguishing feature here is that following randomization, a patient is assigned to one treatment and only one treatment. So the comparison between people who receive Treatment A versus Treatment B is a comparison between different people. Each person only receives one treatment. That's the distinguishing feature of a parallel group design, so that we have independent subjects.

Q. Doctor, let me clarify on Judge Saris' point. A DBRCT, a randomized double-blind placebo-controlled trial, can be either a parallel design or a crossover design, correct?

A. That is correct.

Q. And are parallel group studies, the design shown on the board now, are those typically used to prove efficacy for purposes of FDA approval?

A. Yes.

MR. HOOPER: Slide 11, please.

Q. Now, if you would, please, explain what is a crossover design?

A. So a crossover design is an experimental design in which the same patients receive both treatments, typically in a counterbalanced order. So in one group they will receive Treatment A first, and then after that there may be a washout period, and then they'll receive Treatment B. And in the other

half of the study, half of the subjects who are randomized to Patient Group B, they receive Treatment B first, and then they receive Treatment A following that. So it's the same patients who are repeatedly measured under both Treatment A and Treatment B.

Q. Are there any advantages or disadvantages to using a crossover design?

A. Conceptually the advantage of a crossover design is that we're controlling for other kinds of exogenous factors like age and sex and race and other factors that might add variability to the between-group comparison in a parallel group design.

The disadvantage of a crossover design is that there are carryover effects. If a patient gets better on Treatment A, they're not going to get that much better on Treatment B because they're already better on Treatment A. And that's one of the limiting features of crossover designs and why they're typically not used, for example, to seek FDA approval.

Q. Did you, like Dr. Perry, analyze combined data from several studies in this case?

A. Yes, I did.

Q. Is there an advantage to combining study results as opposed to looking at them one by one by one?

A. One of the distinguishing features about scientific investigations is to determine whether or not the results are reproducible across studies. So an important approach to

understanding a particular result is to see whether or not it stands up, whether or not it's reproducible from study to study to study.

Q. The jury has heard a term called "meta-analysis" at a certain point. Is there a difference between the combined analyses that you and Dr. Perry did and meta-analysis?

A. So the distinguishing feature, and this is a little tricky, is that in meta-analysis we're combining summary statistics from studies, typically based on published studies or study reports. And so we're combining things like effect sizes, which are differences between averages relative to their variability, or differences in proportions. A combined analysis then goes back and is not meta-analysis but goes back to the original data and treats all of the different studies as if they were one large multicenter, multi-study clinical trial, preserving the individual measurements at every single point in time for each individual. It's an advance beyond the kinds of meta-analyses that are used when only the published reports are available.

MR. HOOPER: Slide 12, please.

Q. Let's get into your analysis of the data from pain studies. Can you briefly explain what patient outcomes you chose to measure to assess whether Neurontin was effective or not.

A. I looked at three primary patient outcomes. One was the

likelihood of reporting moderate or greater improvement in pain, a very clinically interpretable kind of outcome. I looked at changes in patient-reported pain scores, the raw pain scores from the original reports. And then I also looked at the more clinically interpretable 50 percent or more reduction in patient-reported pain. And then, finally, in putting these together with adverse events, I looked at the benefit-to-risk ratios for various treatment options across these studies.

Q. Is there any significant difference between the outcomes you chose to look at and those that Dr. Perry chose to look at?

A. No. These are the same outcomes.

MR. HOOPER: Slide 13, please.

Q. For the first outcome, moderate or greater improvement in pain, is that an outcome measured on the PGIC scale that you told us about earlier?

A. Yes, it is.

Q. And which studies did you combine to evaluate moderate or greater improvement in pain?

A. I combined the seven studies that were also combined by Dr. Perry: the Backonja study, the Parsons study, the Reckless study, the Rowbotham study, the Rice study, the Gordh study, and the Serpell study.

Q. The Gordh study is also referred to as the POPP, P-O-P-P, study?

A. That's correct.

Q. And all of those seven had the PGIC scale data that you needed to look at this particular outcome?

A. That's correct.

Q. The jury has heard a lot about a Gorson study. Did the Gorson study have PGIC data that you could use?

A. No. That study did not collect the PGIC, so it couldn't be combined with these others.

Q. Let's turn to the results that had the PGIC data.

MR. HOOPER: Slide 14, please.

Q. Dr. Gibbons, would you please explain what's shown on this chart step by step beginning with the vertical line on the left that's labeled "Odds Ratio." What's an odds ratio?

A. An odds ratio is the relative likelihood or probability of obtaining a patient-reported outcome of moderate or greater improvement in gabapentin-treated patients relative to placebo-treated patients. So, for example, for the Backonja study, we see that the odds ratio is 3, which indicates that a patient is three times more likely or probable to report a clinical improvement of moderate or greater relative to placebo.

Q. And, Doctor, there are gray lines that sort of run vertically through the center of each bar. What do those represent?

A. The gray lines represent the confidence intervals that surround our estimate of the odds ratio. If that confidence

interval is larger than the value 1, it means that it's statistically significant. What that means is that the probability that that could have occurred by chance is less than 5 percent.

So what we see in looking at all of these blue -- and if I get the colors wrong, I'm very color-blind, so I apologize in advance -- if you look at these blue bars, you see that numerically in every single case, for each study individually, the odds ratio is greater than 1. An odds ratio of 1 means that there's an equal chance of reporting this positive outcome for people treated with placebo and people treated with active drug.

Of the seven studies, all of them have odds ratios greater than 1, indicating greater efficacy of gabapentin relative to placebo. This is a very consistent finding. Six of the seven individual studies actually report statistically significant odds ratios; that is, odds ratios that have less than a 5 percent chance of actually being a value of 1, indicating equal likelihood of benefit from placebo and from active treatment.

Q. What's your conclusion based on these data from these seven studies?

A. The overall conclusion is listed on the right in terms of the overall odds ratio pooled across these seven studies, which indicates that there is a two-and-a-half times greater chance

of obtaining moderate or greater improvement on gabapentin relative to placebo. The confidence interval is quite a bit larger than the value of 1, indicating that this is a statistically significant difference, and the likelihood of it occurring by chance alone is very, very remote. The only thing I can't tell you is what color that overall bar is.

Q. I represent to you it's orange.

A. Thank you.

MR. HOOPER: Slide 15.

Q. Doctor, the jury has seen some data presented by Dr. McCrory in the form of what's called a "forest plot." Is this a forest plot?

A. Yes, it is. It presents the same information that was presented on the previous slide, again showing that there is numerical superiority for every one of the individual studies in favor of greater benefit of gabapentin relative to placebo. Six out of seven of the studies show statistically significant benefit relative to placebo, a very consistent result across the studies. And the overall analysis shows consistent benefit for gabapentin relative to placebo, and a confidence interval which is nowhere near the value 1, indicating that this result is statistically significant.

MR. HOOPER: Slide 16, please.

Q. Let's turn now to the next outcome you evaluated, a benefit-to-risk ratio. Can you explain to the jury what you

mean by the term "benefit-to-risk ratio."

A. When deciding whether or not a patient should take a medication, it's very important to weigh the benefits of that medication relative to the risks of that medication. Physicians do this, economists do this, and statisticians do this. So we want to make sure that the benefit of taking a drug far outweighs the negative consequences of taking that drug.

MR. HOOPER: Slide 17, please.

Q. Doctor, I see that this says "Benefit-to-risk ratio using Dr. Perry's calculations." What does that mean?

A. So we're looking at benefit in terms of the percentage of patients that will report moderate to greater improvement in the PGIC in terms of the reduction of their pain based on Dr. Perry's computations. In reviewing Dr. Perry's report, I realized that there were approximately 170 patients who didn't even have PGIC measurements, but Dr. Perry attributed to those patients an outcome that indicated that they had not received moderate to greater benefit, an attribute that couldn't possibly be supported by the data because they didn't have the data. So based on his computations, we see that there is a difference of approximately 38 percent of the patients reported moderate or greater improvement on gabapentin relative to only 20 percent on placebo.

By contrast, to the right we see the risk portion of the

equation. These are the percent of patients who withdrew from the study due to adverse events. It's important that we consider serious adverse events in which the patient decided that whatever benefit they were getting from treatment just wasn't worth it. They just were not going to continue the study because the adverse effects associated with treatment or placebo control outweighed the benefits that they were getting.

In this case, we see that 11 percent of the patients on gabapentin withdrew from the study, whereas 8.1 percent of the patients on placebo withdrew from the study for adverse events. This difference is 2.9 percent, which is very small relative to the increased benefit. If you just simply take a ratio of those differences, you see that the benefit-to-risk ratio is approximately six to one.

MR. HOOPER: Slide 18, please.

Q. Now, this slide looks similar but says "Benefit-to-risk ratio using Dr. Gibbons' calculations." Could you explain what the difference is between this and the previous slide.

A. So in this slide I remove the data from those 170 subjects who didn't have the PGIC. I didn't attribute any outcome to them, either positive or negative. And as you can see, there's small changes, but now the benefit-to-risk ratio is approximately seven to one. There's a larger difference, almost a doubling of the benefit for a very small increase in the risk, only 2.9 percent increased risk to almost 20 percent

increased benefit.

MR. HOOPER: Slide 19.

Q. And now side by side, is there any significant difference between your figures and Dr. Perry's as to benefit-to-risk ratio?

A. We would both come to the same or both should come to the same conclusions regarding the fact that the benefit greatly outweighs the risk, either based on his computations or my reanalysis of his data.

MR. HOOPER: 20, please.

Q. Let's now look at the third type of pain outcome you evaluated, changes in patient-reported pain scores.

MR. HOOPER: Let's go to Slide 21, please.

Q. Can you explain the studies that went into this analysis and why.

A. So at this point I felt that it was important to go back to the original data and reanalyze the data. This is in sharp contrast to everything that you've heard so far that are essentially meta-analyses of the published or unpublished reports that are taking summary statistics and combining them. Here I actually went back to the patient-level data: What happened to Patient 129 on week three of the study in terms of the raw pain score that was reported? And what we can see here is that there were six of the studies that were parallel group studies, all in which they were treated for some form of pain,

so a common indication, and all of which were comparisons of gabapentin relative to placebo, so a very homogeneous group of studies for similar indications with a common treatment. And overall in the intent-to-treat population, which I'll explain in a moment, there were 1,739 patients with a total of 14,114 individual measurements. This is a huge database. This is a tremendous amount of information by which to judge the effectiveness of gabapentin relative to placebo.

The intent-to-treat population means that anybody who was randomized to placebo or active treatment was included in this analysis, a longitudinal analysis that included every single observation available from every single one of those patients. So the intent-to-treat population, the population that's favored by the U.S. FDA, is the most comprehensive population to analyze. It doesn't just involve people who the doctors felt had received enough treatment to show a benefit or patients who had made it to the end of the study. Anybody who was randomized is included in this analysis, and why that's important is, it minimizes bias.

Q. Doctor, just briefly before I move on, I want to make sure the jury understands why Gorson and Gordh, or the POPP study, are not in this analysis. Can you explain why?

A. Those studies were crossover studies, so they were not parallel group studies that would allow us to combine the information, to go back and do this reanalysis of similar

design studies.

MR. HOOPER: Slide 22, please.

Q. Doctor, does this chart show changes over time in average pain scores in the intention-to-treat or ITT group of patients that you just told us about?

A. Yes, it does.

Q. Can you explain for the jury what this chart shows about those pain score changes.

A. So the squares are the observed means, the average pain score at each point in time for all patients that were available at that particular point in time; and the curve that passes through the squares is the estimated curve from the statistical model, and as you can see, it fits the observed data quite well. And the curve at the top is for the placebo patients, showing that they start out at around 6.5 and end up at around 5.5 in terms of their average pain score. And the curve at the bottom is for the gabapentin-treated subjects, again starting out similarly at baseline at around 6.5 and coming down to a score slightly under 4.5.

The probability associated with the question or hypothesis that those two lines are the same, that there is no difference between gabapentin and placebo, has an associated probability of 1 in 100,000, indicating that it is extremely unlikely, given the 1,700 subjects that went into constructing those curves, that those two curves are the same. In terms of the

magnitude of the effect, the rate at which pain goes away in gabapentin-treated subjects is 61 percent faster than it is for placebo.

Q. Are you aware that Dr. Perry said in his report, and I'll tell you here, that the changes in pain scores were statistically significant but clinically meaningless? Are you aware that's his opinion?

A. Yes, I am.

Q. What is your response to that?

MR. SOBOL: Objection.

THE COURT: Overruled.

A. I don't understand why he would attribute that. We've looked at and he's looked at three different kinds of end points: a 50 percent reduction in pain, achieving a moderate to greater reduction in pain, and the absolute change scores. All of them show statistically significant differences. All of them are clinically interpretable. These are large differences. These are as large as I have seen for most drugs that are treating pain or other kinds of subjective disorders. If I were suffering from pain, I would be happy to take this drug.

With respect to the average difference at the end of the study, Dr. Perry was concerned that the difference was anywhere from, I think he quoted .78 to maybe 1.2, and that this is an 11-point scale. And so a 1-point change on average in an 11-point scale is not very meaningful.

There are two problems with that. The first is that --

MR. SOBOL: Objection.

THE COURT: Yes, this is a narrative. I think you need to ask another question.

Q. What is the problem with Dr. Perry's conclusion that a 1- or 2-point difference on an 11-point scale is not clinically meaningful?

A. The patients are using a much smaller amount of the scale. The average deviation from the mean is about 2, so the patients are generally using about 4 to 5 points on this scale, not all 11 points of the scale. So a 1-point change on average in a 4-point scale or a 5-point scale is actually a very large effect.

MR. HOOPER: Slide 23, please.

Q. Let's turn to your fourth pain outcome, a 50 percent or more reduction in pain, Slide 24. Doctor, can you please explain what this chart shows starting with the left axis labeled 0 to 40 percent.

A. So based on the reanalysis of all of the available data, the individual data points, I can estimate at week nine the percentage of patients that would achieve a 50 percent or greater reduction in pain, whether they actually made it to week nine or didn't make it to week nine; and we see that based on the intention-to-treat population, everyone who was randomized, we have a difference of 33.4 percent achieving that

on Neurontin versus 18.7 percent on placebo.

On the right we --

THE COURT: This includes people who stayed in the study, or you're predicting people who dropped out?

THE WITNESS: It includes people who were actually available at week nine, and it also includes the effects of those patients who might have dropped out at week seven.

THE COURT: How do you know then?

THE WITNESS: We have an estimate of their rate of change, of the curve for each individual subject, and we can project that to week nine for those subjects that did drop out. Most of the subjects had a week nine score, so that score is used to compute these percentages.

MR. HOOPER: Can we go back to the previous slide so we can clarify that point.

Q. Doctor, on the slide we were looking at earlier, there are squares for "observed" and a curve for "estimated." Did you take both into account?

A. Yes, I did.

Q. And observed are actual measurements?

A. The observed are actual measurements.

MR. HOOPER: Now if we could go forward to Slide --

THE COURT: Could you go backwards just one second.

MR. HOOPER: Sure.

THE COURT: Just the difference between the -- so the

ones you actually observed, the line that says "estimated" are the ones where you projected the people who dropped out?

THE WITNESS: The "estimated" is the estimated curve for the average of all gabapentin-treated subjects on the bottom and all placebo-treated subjects at the top. The statistical model also provides an estimated trend line for each individual subject.

THE COURT: I was probably unclear. So does the "estimated" include the people whom you didn't actually observe but you're projecting?

THE WITNESS: That's correct.

THE COURT: Okay. But the "observed" are people you actually had?

THE WITNESS: Exactly.

THE COURT: That's the better number?

THE WITNESS: Well, the "observed" is an important number. The "estimated" is an important number also, and let me explain. The "observed" is everybody who was available at the end of treatment. Now, some of these patients may have dropped out of treatment because they were doing so well, they really didn't want to continue the study; and other patients may have dropped out of the study because they really weren't getting any benefit of the drug or placebo, and they decided that they didn't want to stay in the study. So the most complete analysis uses all the available data from every

subject so it's not biased by only looking at those people who made it to the end.

THE COURT: I just want to understand the term.

I'm asking all the questions. Where are you? You're asleep this morning. I'll have to pump you with caffeine because, you know, this is a chance to ask the folks questions.

All right, go ahead.

MR. HOOPER: Let's go to Slide 25, please.

MR. SOBOL: We've got a question, your Honor.

THE COURT: All right.

A JUROR: Going back to the curve where you took the data and you curved it with that curve, that's the estimate?

THE WITNESS: That's correct.

A JUROR: Now, those two curves, they look fairly similar except there's a translation from one to the other.

THE WITNESS: That's correct. The form of the curves is very similar. The model that's used to fit those curves is the same in both groups, and in fact the data are well fitted by those curves; but the slope, the rate of change is very different. The rate of change in the curve below is 61 percent faster than the rate of change in the curve above.

A JUROR: That's tough to pick out when you're looking at the rate of change in the curve, 61 percent, whatever that is, okay. But, again, maybe I'm misinterpreting it, but the top one was the placebo effect?

THE WITNESS: The top one are those patients who were in placebo. So we see that --

A JUROR: They seem to be over 40, so higher pain scores along the way.

THE WITNESS: That's a very good observation. Even early on in the treatment, after one week, the patients on active treatment are doing better, clearly numerically, than the patients who were randomized to placebo. There's remarkably good separation between these curves, even early on in treatment, and, more importantly, that separation is maintained at the end of treatment.

MR. HOOPER: Slide 25, please.

Q. Returning to the 50 percent or more reduction in pain, Doctor, could you explain the results and whether it was statistically significant.

A. So if we compare these percentages of 33.4 percent in the intent-to-treat population who got gabapentin versus 18.7 percent in placebo, the probability that those two percentages by chance alone could have been the same in a sample of this size is 1 in 10,000. So what this indicates is that that difference is statistically significant, way, way beyond what we would expect by chance alone.

Q. Doctor, to sum up to this point, did you test the data for the same pain outcomes that Dr. Perry chose to evaluate?

A. Yes, I did.

Q. Were the results similar for all four?
A. Yes, they were.
Q. Did the results favor Neurontin in all four?
A. In all cases, yes.
Q. Let's turn to your second major opinion dealing with Dr. Jewell's theory about unblinding in the Backonja study in diabetic neuropathy. First, just to reacquaint us with it, can you remind us, the jury, and Judge Saris of Dr. Jewell's unblinding theory as you understand it.
A. Yes. The idea of unblinding is not a theory attributed to Dr. Jewell. It's a common question related to subjective measurements. The concern is that active medications will produce side effects. Placebo, also patients report side effects. Once you obtain, once you experience the side effect -- let's say, for example, that side effect is a headache -- all of a sudden you say to yourself, "Ah, I got a headache. I must be on the active treatment. I'm lucky, I've got the treatment, so I think I'm going to get better because I know that I'm getting the real treatment, and I'm not going to embarrass myself by having my pain go away simply being on placebo."
MR. HOOPER: Slide 27.
Q. Turning briefly to the Backonja article that appeared in the Journal of the American Medical Association, was unblinding brought up in the article itself?

A. Yes. The authors of this study discussed unblinding as a possible explanation for the difference between placebo and active treatment, and they did a series of analyses to insulate themselves from the bias that could be produced by unblinding by eliminating patients who had experienced a particular side effect.

MR. HOOPER: And then if we could go to Slide 28 and go up to 29, if you will.

Q. When you analyzed the unblinding hypothesis for the Backonja study, did you analyze it the same way Dr. Backonja did in the JAMA article?

A. No, I didn't. What Dr. Backonja did was to look at each class of side effects. There really were three classes of side effects: There was sleepy, dizzy, and twitchy. That's how I remember them. Sleepiness --

THE COURT: It sounds like the dwarfs.

THE WITNESS: Exactly. That's my only way of remembering all of them.

And what Dr. Backonja did, and Dr. Jewell objected to it, and I think a reasonable objection, was that he looked at each class of side effects separately. So he took all the sleepy people, and he took them out and reanalyzed the data and still found that the drug was efficacious. Then he took out the dizzy people and reanalyzed the data, but he put the sleepy people back in. And then he took out -- well, I think he only

looked at dizzy and sleepy.

In my analysis, I included all three classes of side effects simultaneously in the analysis, but I preserved their individuality and actually estimated the relationship between the emergence of those side effects and pain scores. I did that simultaneously for all of them, and then I also did that pooling all of them together into one big side effect pot like Dr. Jewell did.

Q. What did you find when you adjusted for the emergence of all CNS side effects?

A. The first thing that I found was, there was no overall relationship with CNS side effects and the pain scores. That is, the averages didn't change before and after the emergence of those side effects, so it couldn't possibly be unblinding.

I also then looked at the individual side effect classes simultaneously in the statistical model and found that for sleepy and dizzy, there were no association with the changes in pain score, but for twitchy, there was actually a positive association. Those patients who reported nervousness actually had worsening of their pain, not lessening of their pain, in the data. So --

Q. Is that consistent or inconsistent with an unblinding?

A. It's the absolute opposite of unblinding. Unblinding would have had a relationship where once the side effect occurred, the pain scores would go down. There would be less

pain because the patient would now know that they're on active treatment.

Q. In unblinding, is the improvement in pain supposed to come after you develop the side effect?

A. That's how we test for unblinding.

Q. Did you consider whether there was pain improvement in these patients before the side effect occurred?

A. Yes, I did. And in fact the improvement in pain in those patients who experience the side effect occurred before they ever experienced the side effect.

A good analogy is chemotherapy and losing your hair. If you're on high-dose chemotherapy and you don't lose your hair, you know that they haven't given you enough chemotherapy. Losing your hair is a marker of the biological activity of the drug, and in this case, having essential nervous system side effect is a marker of the biological activity. The patients who experienced the CNS side effects in fact were those patients who received the greatest benefit of treatment, the greatest pain reduction, prior to the emergence of the side effect, not after the side effect emerged.

MR. HOOPER: 33.

Q. Let's turn now, Dr. Gibbons, to your third major opinion on Dr. McCrory's conclusions about migraine headache.

MR. HOOPER: 34, please.

Q. Do you recognize this as the results from Dr. McCrory's

report where he combined the results of three headache studies?
A. Yes, I do.
Q. What's your interpretation of his results as shown in the forest plot here?
A. The interpretation is that there is a trend towards increased efficacy in terms of 50 percent reduction in headache frequency in Dr. McCrory's analysis. The result is not statistically significant. You can see that there's a slight overlap of that diamond at the bottom, which is the overall result that includes the value 1. The associated probability is .145. Because it's not less than 5 percent, we can't say that it's statistically significant, but it's in the direction that we've seen for the other pain end points.
THE COURT: Could you say that again? So is it effective or not effective for migraine?
THE WITNESS: So there's a trend towards effectiveness, but we can't conclude that that trend is statistically significant because the confidence interval for the odds ratio includes the value 1.
THE COURT: Right, so you can't say scientifically?
THE WITNESS: I can't say statistically that it is -- you know, there's still a 14 percent chance that the true value is 1, that the true value that there's no effect is 1. For it to be statistically significant, we'd like that probability to be less than 5 percent. So we describe this result as a trend

in that direction, but it's not a statistically significant trend.

Q. Just based on these three studies, correct?

A. That's correct.

Q. What would happen if instead of three studies there were three identical twin studies with them that made for six with the identical result?

MR. SOBOL: Objection.

THE COURT: Sustained.

MR. HOOPER: Go up to Slide 35, please.

Q. Doctor, can you explain what this chart shows, and particularly the two orange bars on the bottom?

A. This is my reanalysis of those data using a more complete statistical model, and it shows that the odds ratio went from 1.54 to 1.62. It's a little closer to being statistically significant but still not statistically significant, again, showing a fairly similar trend as Dr. McCrory found for the analysis of these three studies.

MR. HOOPER: Go to Slide 36, please.

Q. You cited in your report a study we talked about with Dr. McCrory when he was here, a study by a Dr. Trapani and others from Italy. You're familiar with the Trapani study?

A. Yes, I am.

Q. And, first, is there a principle in science called "consistency"?

A. Yes.
Q. Can you explain to the jury how consistency would apply here.
A. Well, the foundation of science is reproducibility --
MR. SOBOL: Objection, your Honor. Beyond the scope, another report.
THE COURT: The word "consistency"? I'll allow that. Go ahead.
MR. SOBOL: Well, I think it's leading to something, but go ahead.
THE COURT: Go ahead.
A. The simple point is that we want to for any scientific finding show that it's reproducible in other people's hands, and this is a study that shows that the effect that we observed that was a trend in the direction of decreased headache frequency, when expressed as 50 percent or more in both Dr. McCrory and my analysis, is further substantiated by the results of the Di Trapani study that showed statistically significant reduction in overall headache frequency.
Q. And was this a study in migraine prophylaxis or prevention?
A. Yes, it was.
Q. And, again, what were the results?
A. The results showed that gabapentin led to a statistically significant decrease in the frequency of migraine headache

pain.
Q. And this was a randomized double-blind placebo-controlled clinical trial?
A. Yes, it was.
MR. HOOPER: Slide 37, please.
THE COURT: Were the other three DBRCTs as well?
THE WITNESS: Yes, they were.
Q. And, Doctor, you also cited in your report a study by Dr. Spira and colleagues from Australia. Was this a study in a condition called "chronic daily headache"?
A. Yes, it was.
Q. Was this also a randomized double-blind placebo-controlled clinical trial?
A. Yes, it was.
Q. And what result did this trial find for gabapentin and chronic daily headache frequency?
A. Again, reproduced the effects observed by Di Trapani, showing a statistically significant reduction in the frequency of headaches with gabapentin relative to placebo.
MR. HOOPER: Slide 38, please.
Q. And does the Spira study describe a relationship between chronic daily headache and migraine?
A. Yes. They describe it on the same continuum.
THE COURT: Could you just say that. What is CDH?
MR. HOOPER: Chronic daily headache.

THE COURT: Headache. Is that a migraine?

THE WITNESS: It's kind of a mini migraine, as I understand it. I'm not an expert in that, but the authors described it sort of as a threshold on the continuum of migraine headache. It's a chronic daily headache. It's a headache that keeps recurring.

MR. HOOPER: Slide 39.

Q. Dr. Gibbons, what is your opinion as to the efficacy of Neurontin or effectiveness of Neurontin in neuropathic pain relative to Dr. Perry's?

A. My findings and my interpretation of Dr. Perry's findings are very consistent. We see that regardless of the end point, be it individual pain scores, or 50 percent reduction in pain scores, or achieving a moderate to greater benefit in terms of the reduction of pain scores, there are both statistically significant and clinically significant differences that show clearly that gabapentin is efficacious in the treatment of neuropathic pain.

Q. Doctor, what is your opinion on Dr. Jewell's unblinding hypothesis as to the Backonja study?

A. The data clearly do not support an unblinding hypothesis. First, the benefits in pain occurred before the emergence of the side effects. Second, the side effect of nervousness actually led to increased pain, not to decreased pain. And, finally, and perhaps most importantly, there was no evidence of

change in pain in the control group. The control patients, the placebo patients, experienced CNS side effects, but they did not experience any change in pain. Unblinding occurs both for treated patients and control patients. Anyone who experiences the side effect should then experience a reduction in pain. It shouldn't be restricted to the treatment arm.

Q. What is your opinion vis-a-vis Dr. McCrory as to effectiveness in migraine headache?

A. Based on his analysis and my reproduction of that analysis, I find very similar results to Dr. McCrory, and my interpretation of that is a trend in the direction of increased benefit. When you add in the Di Trapani study and the Spira study, what you see is that this is a reproducible effect; and in these other two studies, even individually, there are statistically significant improvements.

Q. Doctor, do you hold each of those opinions to a reasonable degree of scientific certainty?

A. Yes, I do.

MR. HOOPER: Pass the witness.

THE COURT: Let's stand and stretch for a second.

(Pause.)

THE COURT: All set? Let's go.

MR. SOBOL: May I inquire, your Honor?

CROSS-EXAMINATION BY MR. SOBOL:

Q. Sir, will you please tell the jury when you first started

taking money from Pfizer and Parke-Davis to defend it in Neurontin claims?

A. I don't know off the top of my head, but it's probably been two years maybe, a year and a half, something like that.

Q. So for about a year and a half, two years, you've been taking money actually from the Pfizer lawyers to defend it in Neurontin claims, correct?

MR. HOOPER: Object.

THE COURT: Sustained just to phrasing.

Q. Well, have you ever met anybody from Pfizer in connection with your work?

A. Uhm, I believe I met in connection with the litigation some of the -- one or more of the lawyers who work directly for Pfizer, yes.

Q. Other than lawyers, have you met anybody else from Pfizer?

A. I think I may have, you know, but --

Q. Did you meet anybody from Pfizer today when you were here in the court? Is there anybody from Pfizer here today?

A. Uhm. . .I recognize him.

Q. Okay. And who is he?

THE COURT: It's like a Perry Mason moment.

(Laughter.)

Q. Who is he?

A. Well, I think he's one of the lawyers for Pfizer.

Q. Apart from lawyers, have you ever met a nonlawyer from

Pfizer in connection with your work? Yes or no.
A. I have not worked with the drug companies as a consultant, no.
Q. Isn't it fair to say, sir, that you made almost $400,000 last year from Pfizer counsel defending it in Neurontin claims?
MR. HOOPER: Objection.
THE COURT: Overruled.
A. I don't know the exact amount. That may be correct. I never expected to be spending as much time in this courtroom when I took on this job.
Q. I'm not asking a time limit. I asked you a very simple question. You're a statistician. Isn't it fair to say that you made approximately $400,000 last year paid to you by Pfizer lawyers to defend it in Neurontin claims?
A. I don't know if it's $400,000, so I can't really answer that question.
Q. We have some of your bills. Can you go to a --
MR. SOBOL: Can I have a binder for his bills.
May I approach, your Honor?
THE COURT: Yes.
Q. Sir, I put before you a photocopy of some bills that you provided some other lawyers in this litigation. Those are your bills, correct? Yes or no.
(Witness examining documents.)
Q. Yes or no.

A. I can't say that -- you've handed me a large group of paper. You know, I can't say that they're all my bills unless I look at them.

(Witness examining documents.)

MR. HOOPER: Your Honor?

THE COURT: Yes.

MR. HOOPER: Can we have a very brief side bar on these?

THE COURT: Is this about that this is a bigger --

You know, I just want to remind you that without going into the details, this is a huge litigation that has many subparts, and this is one part of it. But Dr. Gibbons -- is this the point? -- may have been involved, in fact I know for a fact was involved in other parts, other cases being brought involving Neurontin. So I think Mr. Sobol's question goes to all the litigation as a whole, right?

MR. SOBOL: Correct.

THE COURT: All right, just so there's no confusion here.

A. Yes, what you've put in front of me are my invoices.

Q. And are you charging $500 an hour?

A. That's correct.

Q. And you do all the work yourself, correct?

A. That's correct.

Q. Nobody else helps you at any point in time in connection

at least with the work that you did in this case, for this case, the purchase and claim case, correct?

A. I believe that to be correct. I did have some help in one of the other cases.

Q. And I noticed when I went through these bills, I noticed that you never work a half of an hour or a third of an hour. It's always just to the rounded hour; is that correct?

A. That's correct.

Q. And I also noticed, by the way, when I go through these bills, it's usually billed eight hours or fifty hours, forty-four hours, forty hours, thirty-two hours, all sort of even number hours rather than odd number hours. Do you always work an even number of hours rather than an odd number of hours, or do you round to the even hour also?

A. I believe there's a -- in the one in front of me, I have three hours. I believe that's an odd number.

Q. Correct. And I also found one other time, another time where there was an odd number, but nowhere else in these bills did I see you working an odd number of hours. Is that a habit of yours?

A. My billing habits are to work for typically the course of a day or whatever is required. Many times if I have worked nine hours, I bill for eight hours. It's usually the work I do on these sorts of things consumes either a half of my day or all of my day, and I bill accordingly.

Q. Okay. So as a statistician, you round to the every even hour when you're billing?
A. The data in front of me suggests that that's not the case.
Q. Now, you're not a medical doctor, correct?
A. That's correct.
Q. You've never practiced medicine, correct?
A. Definitely not.
Q. You never treated anybody with migraine?
A. No.
Q. Or with nociceptive pain?
A. No.
Q. Or neuropathic pain?
A. No.
Q. You've never led a clinical study that involved the study of pain, whether nociceptive, neuropathic, or other, correct?
A. I've participated in studies as a study statistician.
Q. Have you led a study?
A. No, I haven't led a study.
Q. Have you led a study in migraine?
A. No.
Q. In this case you know that there are some other people who have opined. For instance, Dr. Perry, you know that he is a medical doctor too, correct?
A. I know that he is a medical doctor.
Q. You know that Mr. McCrory is a medical doctor, correct?

A. I believe so.
Q. You also know that Dr. Abramson, did you review any of the material of Dr. Abramson to critique his analysis of pain or migraine?
A. Not that I recall.
Q. In any event, in this case, I think you testified that Pfizer gave you some underlying data, didn't it?
A. That's correct.
Q. In fact, was it hard for you to get the data?
A. I actually asked Pfizer to get the data.
Q. And did they say, "No, we can't give it to you"?
A. No. They were quite compliant in giving me the data.
Q. No reluctance on their part at all to give you the data, correct?
MR. HOOPER: Objection.
THE COURT: Sustained.
Q. So when you asked for the data, you asked for all of the underlying data regarding, I think, each of the pain studies, correct, that you were going to look at, correct?
A. I asked for all of the underlying data for the parallel group randomized placebo-controlled trials.
Q. Okay. Now, are you aware of a group call the Cochrane Study or the Cochrane Collaborative or something like that?
A. Yes.
Q. Please tell the jury, do you think that's a fairly well

regarded collaboration or effort or not?

A. Well, personally I think that the Cochrane Collaboration uses some of the wrong statistical models. Some people regard them highly; other people don't. They're meta-analyzers, and they typically review the available data.

Q. Are you aware that the Cochrane Collaborative tried to get the underlying data from the exact same studies that you asked Pfizer to give you the underlying data? Do you know that?

MR. HOOPER: Objection. Assumes facts not --

THE COURT: Overruled. Do you?

THE WITNESS: No, I don't know that.

Q. Do you have any reason why it is that Pfizer or its counsel might trust you with the data but won't trust Cochrane with the data?

A. No.

Q. Have you always been truthful about your relationship with Pfizer?

A. I believe so, yes.

Q. Do you recall writing a letter to the editor of the Archives of General Psychiatry in March of 2009?

A. No.

MR. SOBOL: What number is it in the book?

Q. If you go to the tab March 15, 2009, in the binder that's in front of you, please.

MR. SOBOL: Can we put that up on the screen.

Q. Do you recall this letter?
A. It looks like a letter I wrote. I don't remember it offhand. I can read it.
Q. Well, let me draw your attention then to one particular thing, since we are on a time. In the second full paragraph --
MR. HOOPER: Objection, your Honor. We need a side bar.
THE COURT: All right.
SIDE-BAR CONFERENCE:
MR. HOOPER: The objection to this is, it's not an exhibit, it's not disclosed. They're displaying it to the jury.
THE COURT: Yes, that will come off. That's the rule.
MR. SOBOL: It was disclosed.
THE COURT: Excuse me. We have the rule straight up. It can't be on a screen unless it's an exhibit. Now, you can ask about it.
MR. SOBOL: Or a chalk. But I'll ask about it. That's fine.
THE COURT: So who's doing the documents? Are there any others like this?
MR. SOBOL: I'll talk to Corinne about it.
THE COURT: Okay.
(End of side-bar conference.)

BY MR. SOBOL:

Q. Sir, on or about March 15, 2009, did you write a letter to the editor --

THE COURT: Have you had a chance to look at that letter now?

THE WITNESS: Yes, I have.

Q. On that date, did you write a letter to the editor of the Archives of General Psychiatry, which, by the way, is at your own institution, the University of Illinois? You wrote them a letter, right?

A. What's at my own institution?

Q. I'm sorry. You wrote a letter to the editor of the Archives of General Psychiatry on or about March 15, 2009, correct?

A. Correct. This was about a paper that we had submitted.

Q. And then didn't you tell that editor -- he was considering whether or not to accept for publication something that you wanted to get published in his journal, correct?

A. That's correct.

Q. And you were trying to make a full and complete disclosure about your relationship with Pfizer at the time that you did that, correct?

A. I was making a --

Q. Yes or no.

A. Well, it's not just Pfizer. It's also the U.S. Department

of Justice. It's also Wyeth.

Q. I asked just about Pfizer. We're not talking about everything else in the letter, about Pfizer. Isn't it fair to say that you were trying to tell the complete and honest truth about your relationship with Pfizer in this letter?

A. Yes.

Q. You say about somewhere in the second paragraph here, probably about ten lines down or so where it says, "I was paid for my time as an expert witness." Do you see where I'm beginning to read here?

A. Yes, I do.

Q. You say, "I was paid for my time as an expert witness for my analysis of the gabapentin data, but I have not been paid by Pfizer for my work on the bipolar cohort which forms the basis of the paper that you are currently reviewing."

Did I read that correctly?

A. Yes, you did.

Q. Did you tell that editor that at that time?

A. Could you repeat the your question?

Q. I'll repeat the question. I'll ask it this way: You lied to him, didn't you?

A. No, of course not.

Q. Well, let's go to your bills. Can you please go to your bill for August 6, 2008.

MR. HOOPER: Can we have a copy?

THE COURT: Is that part of the documents that you've been --

MR. SOBOL: Yes.

MR. HOOPER: It wasn't produced to us.

MR. CHEFFO: The letter, Mr. Sobol.

THE COURT: Was that disclosed last night, the letter?

MR. SOBOL: Yes, it was, your Honor. It was also produced by their witness.

Q. Now, sir, isn't there a bill in August 6, 2008, to Pfizer counsel that says "Construct statistical database, compute summary of statistics, and perform screening analyses for BP cohort, 50 hours, $25,000"? Yes or no.

A. Yes.

Q. Let's turn to your opinions about Professor Jewell. First, it's fair to say that it's not Professor Jewell that came up with this notion about the potential unblinding in the Backonja study, correct?

A. Correct.

Q. All right. This isn't something that he particularly made up. It's an issue that even Backonja himself was struggling with. True?

A. True.

Q. Okay. Now, you're aware, of course, that Dr. Backonja is probably in a better position than you to decide what's clinically important and what's not clinically important in

terms of changes in pain scores, correct?
A. Certainly Dr. Backonja who's a physician understands the clinical nature of this better than I do. My analysis is a more complete analysis of the data, and so I would feel that --
THE COURT: At this point, though, we're trying to finish you up, so answer his question.
So why don't you ask the question again.
Q. Dr. Backonja specializes in studying pain, correct?
A. Correct.
Q. Okay. Unlike you, he actually focuses on this quite a bit and spent huge amounts of time, probably even more than you did last year billing $400,000, he spent huge amounts of time on this study?
MR. HOOPER: Objection.
THE COURT: Sustained. Mr. Sobol, just one question. Now, what's the question?
MR. SOBOL: Fair enough.
Q. Sir, isn't it fair to say that Dr. Backonja, that you would understand that his judgment should be respected by this jury in terms of what a clinically important result might be?
A. Yes, I do.
Q. And you made observations, didn't you, when you read the Backonja study as to what Dr. Backonja thought would be clinically important rather than what you might think is clinically important? Did you make that observation?

A. No.

MR. SOBOL: Let me go to my slide.

Q. Did you notice the discussion by Dr. Backonja when he was trying to figure out how to power his study?

A. No.

Q. Okay. First, actually let's go to the -- well, did you notice that, first, that he had written that there were published results in clinical trials that show a wide variation of placebo response, ranging from 10 to 40 percent?

A. No.

MR. SOBOL: Let me go to the Backonja article itself so I can show the witness this, please, first. And then go to Page 1833 on it. It's like three pages in.

Q. Dr. Backonja had to do a power calculation or a power analysis in order to figure out, among other things, how many people to put in the study, correct?

A. That's correct.

Q. And we're dealing here with subjective pain scores, right, so we are concerned by definition about potential unblinding, correct?

A. Correct.

Q. All right. And indeed you also notice that the Backonja study had forced titration, meaning that people kept on getting more and more Neurontin, if they were on the Neurontin arm, up to I think 3,600 milligrams, unless they had reported a side

effect? Do you recall that?

A. I recall there was a titration introduction to the study, yes.

Q. Well, it was called "forced titration" even here.

A. Yeah.

Q. Now, in looking at the power analysis, Dr. Backonja first observed that the -- now that I have this on the screen -- that the placebo response ranged from 10 to 40 percent, correct?

A. Correct.

Q. Okay. And then if we drop down to where it says "Therefore, in this," right, "Therefore, in this trial of 8 weeks' duration, we considered 30 percent a conservative estimate of placebo response, that is, at least an improvement on the CGIC," of 30 percent, correct?

A. Correct.

Q. That's what they expected people who were just getting a sugar pill to improve, correct?

A. Correct.

Q. And then Dr. Backonja wrote, and he was being funded by Parke-Davis at the time, "A gabapentin response of 55 to 60 percent on the same scale would be considered a clinically important finding."

Did I read that correctly?

A. Yes, you did.

Q. Okay. Now, does this refresh your memory about how

Dr. Backonja powered the study and what he thought a clinically important result might be?

A. It certainly seems consistent with that.

Q. Now, when you were doing your write-up, did you try to figure out whether or not the results of the Backonja, even as reported by Dr. Backonja, show that there was a clinically unimportant result in that study? Did you look at that at all?

A. Yes.

Q. Well, let's do that.

MR. SOBOL: Can we go to my chart, please.

Q. Now, I put up a slide. This is obviously not from Backonja's study, the slide itself, but the material is from it. Is it fair to say that he estimated a placebo response of 30 percent, correct?

A. Correct.

Q. And that a clinically important Neurontin response was going to be -- at a minimum had to be 55 to 60 percent, correct?

A. Correct.

Q. Now, when you look at what actually happened over on -- well, first, what the clinically important projection was over on the left here of this screen -- do you see this? -- minimum to be clinically important, they started with a mean pain score of 6.5, correct?

A. Correct.

Q. All right. And a 55 to 60 percent drop had to bring it down to 2.6 or 2.9, correct?

A. Correct.

Q. All right. And what Dr. Backonja said in his study, after review by Parke-Davis many hours, was that a clinically important drop, the kind of thing that really matters on a pain scale of, I think, 11 here -- I think it was 11 -- is a drop of 3.6 to 3.9, correct?

A. Conditional on having a placebo response of 30 percent.

Q. Well, that's what they predicted would be here, 3.6 to 3.9, correct?

A. Yes.

Q. Now, when you look at what ended up happening when they did the study is that the mean pain score started 10 points less, went one-tenth of a point less at 6.4, correct?

A. Roughly.

Q. Right. But it only dropped to 3.9, correct?

A. My estimate would be a little more like 3.5.

Q. Well, I understand that you have gone back and you've redone an analysis, okay. I'm talking about the way that Backonja and the scientists at Parke-Davis reported their results, not your recalculation of things.

A. No, I'm not saying that 3.5 is hugely different than 3.9.

Q. Okay. But, in any event, the drop was only then 39 percent, not clinically important according to the

projection that Dr. Backonja had planned, correct?
A. Oh, I would completely disagree with that.
Dr. Backonja --
Q. No, no, there's no reason to go into an explanation of it. You don't think that there was -- is there a report anywhere about the clinical importance, reporting the clinical importance in the Backonja study rather than statistical importance?
A. In Dr. Backonja's paper --
Q. Yes or no.
A. -- he makes it very clear --
MR. SOBOL: Yes or no, your Honor.
THE COURT: Yes, I'll strike the answer. Listen to his question.
What's your question?
Q. Is there a report in the Backonja study that has at the end in conclusions reporting what the difference was and whether it was clinically important as opposed to statistically important?
A. I don't recall from -- I haven't read that report in a while.
Q. Now, Professor Jewell thought that it made sense that if we want to test an elevator to figure out whether or not it can hold ten men and ten women, it made sense to have all of the men and all of the women on the elevator all at the same time

and run it up and down. Would you agree with that?

A. Yes.

Q. Did you do an analysis where you basically backed out all the dizzy people and all the sleepy people data and simply did a calculation as to what that result from Backonja?

A. I don't understand your question.

Q. You've given some testimony that you did an analysis, and, in your view, some of the report of reduction in pain by some of the people who were getting sleepy or dizzy happened before they got sleepy or dizzy. Do you recall something to that effect?

A. Yes.

Q. Okay. Now, actually, what's more accurate is that there were early drops in pain scores by some people before they reported getting dizzy or sleepy, correct?

A. Correct.

Q. You don't know what was going on in their body when they were taking an active chemical before they reported being dizzy or sleepy as to whether or not it was subjectively causing some kind of unblinding? Fair to say?

A. Not really.

Q. Let's move on to your opinions regarding pain in this case. And if I understand it, you did an analysis --

MR. SOBOL: Can we go to the Elmo for a second, Corinne.

Q. You did an analysis -- excuse my "you excluded." That was on a different part of -- that's when you did the data analysis, you didn't use the POPP data, correct?

A. Correct.

Q. All right, so we'll get rid of that. That was my notes for that part of things.

First, my understanding is that you did essentially two forms of a pain analysis. First you looked at these studies separately, did some recalculations, and you presented some data to the jury about that part of it. That was step one, if you will, of your pain analysis. Fair to say?

A. Yes.

Q. And then step two was, you took the data, the underlying data for six of the seven or so studies, merged them together and gave us a different report. Fair to say?

A. Correct.

Q. When you set out to look at pain in this case, did you inquire as to whether or not anybody at Pfizer had ever done this same kind of an effort before?

A. No.

Q. Were you aware that in 2001, Pfizer and the FDA had looked at the exact same studies that you were looking at last year?

A. I assume that there was a -- if they were seeking an NDA, FDA would look at all the studies.

Q. Well, I guess no assumptions. I really just want to find

out whether you know something or not, okay? Did you know that in 2001, people at Pfizer -- and they actually had about fifteen people show up to one of the meetings -- met with people at the FDA to talk about these same studies?

A. I'm not sure --

Q. Yes or no.

A. I didn't know that, but I'm not sure all of these studies were available at 2001.

Q. Well, Backonja was, correct?

A. Yes.

Q. Rowbotham was. It was discussed. It was published the same time as Backonja, right?

A. I believe so.

Q. Reckless had just been finished, and it was discussed with the FDA in 2001. Did you know that?

A. No, I don't -- I wasn't there in 2001.

Q. Do you know that the Rice study was available and discussed between Pfizer and the FDA in 2001?

A. I didn't know it.

Q. What about the Serpell study, do you know that that too was discussed by Pfizer and the FDA back in 2001?

A. They may have.

Q. Some of these studies are for shingles-related pain, correct?

A. Correct.

Q. Some of these studies are for other forms of neuropathic pain, like for peripheral neuralgia, for instance, right?
A. Correct.
Q. Some of them are mixed, correct?
A. Could be.
Q. In this analysis of pain -- this is a legal expression -- you smooshed all these studies together, correct?
A. I looked at these individually, and then I also synthesized the results for all of these studies on pain.
Q. Synthesized, I can live with synthesized. You wanted to look at these results and synthesize the result and come to a conclusion that Neurontin is good for neuropathic pain as a whole? I mean, that was your opinion, right?
A. Correct.
Q. Now, don't you know that the FDA in 2001 told Pfizer you can't do that?
MR. HOOPER: Objection.
THE COURT: Overruled.
A. I was not making a case to the FDA. What the FDA -- the FDA doesn't do this kind of synthesis. You do this kind of synthesis to know whether or not there is an overall efficacy of the drug. The FDA is looking for two positive randomized controlled trials. It's my understanding that for the shingles-type pain, there were two statistically significant randomized clinical trials, and they were given an indication

for that.

It's also my understanding that at the time, for the diabetic pain, the Parsons study was not available, and there was only one study that was positive that was a randomized clinical trial, and so they were denied an indication for that. The Parsons study, as I understand it, became available after 2001 and would have led to a successful NDA if submitted.

MR. SOBOL: Motion to strike, your Honor.

THE COURT: Denied. I mean, you've got to do it right away.

MR. SOBOL: Okay, that's fine.

Q. So, sir, does the jury deserve from you less of making a case than you would make to the FDA? Is that your testimony?

MR. HOOPER: Objection.

THE COURT: Overruled.

A. My testimony is that these are apples and oranges. The kind of information that goes to getting an NDA for a particular indication --

THE COURT: I strike it. So just as I understand it, so the FDA decided to treat shingles, PHN, differently from the diabetic neuropathy, but you're combining them? Is that the difference?

THE WITNESS: That's correct.

Q. And at no point during your direct examination here today did you point out to the jury that you were combining shingles

studies with peripheral neuralgia studies, did you?

THE COURT: When you say "peripheral neuralgia," are you referring to the diabetic study?

MR. SOBOL: Yes.

THE COURT: So I think on initials, the abbreviations, one was DPN and one is PHN, right? Is that right? Everyone agrees? All right, so that the FDA approved the PHN, the postherpetic neuralgia, is that right? But not the DPN, the diabetic peripheral neuropathy. I think I'm going to get an M.D. after this, but, anyway, is that right?

THE WITNESS: That's correct.

THE COURT: All right, and you, though, decided to combine the studies when you did your analysis?

THE WITNESS: Right. I tried to look at neuropathic pain in general.

Q. And during your direct exam, you did not point out to the jury that you were combining the DPN and the shingles studies, correct?

A. Well, I pointed out to the jury which --

Q. Yes or no.

THE COURT: Yes or no.

A. No, I didn't.

Q. When you set about doing your analysis and giving your testimony to the jury, did you know, yes or no, did you know that the FDA told Pfizer back into the end of 2001 that there's

not sufficient clinical data to support an indication for general neuropathic pain?

MR. HOOPER: Objection.

THE COURT: Overruled.

A. No.

(Pause.)

MR. SOBOL: Thank you. Mr. Rona has given me a note here.

Q. You do understand, sir, that in this case, Kaiser is not seeking damages for postherpetic neuralgia for shingles-related pain? Do you understand that?

A. I'm not a lawyer. No, I don't.

Q. You don't know that?

A. I don't know that.

Q. And so at no point during the several months that you were planning your report and you were synthesizing the shingles studies with the DPN studies were you told, "Hey, wait a second, Kaiser isn't seeking damages for postherpetic neuralgia"?

A. No.

THE COURT: How much longer do you think you have?

MR. SOBOL: I've got quite a bit because we also have to do migraine.

THE COURT: Could you finish by 11:15 or not necessarily?

MR. SOBOL: No, and actually I need to take something for my break, so I need a break.

THE COURT: All right, so we'll take a break.

THE CLERK: All rise for the jury.

(Jury excused.)

(Discussion off the record.)

(A recess was taken, 11:00 a.m.)

(Resumed, 11:37 a.m.)

THE COURT: Let's bring this jury in. Dr. Rothschild is here?

MR. HOOPER: Yes, your Honor.

THE COURT: Seventy pages, but who's counting? And if you delete the signature pages, we could get it down to 65.

MR. CHEFFO: Lots of documents, important issues.

MR. SOBOL: Clearly struggling, your Honor.

THE COURT: Your RICO thing was itself a treatise.

MR. SOBOL: That was an exercise in brevity. 51.

THE COURT: Let me ask you, do you know if the plaintiffs are planning on responding in writing to the judgment?

MR. SOBOL: Yes.

THE COURT: You are. So when would you be --

MR. SOBOL: You would have to speak to the partner who's in charge of that to find out. He's a little timing challenged.

THE CLERK: All rise for the jury.

(Jury entered the courtroom.)

THE CLERK: Please be seated.

BY MR. SOBOL:

Q. Sir, one of the places that we left off were going through some of the studies that you first looked at individually, and then you synthesized the data, correct?

A. Correct.

Q. Now, just to go back over these studies again, briefly, I think it's fair to say that each of these studies, with the exception of Parson's, in the final reported version of Gordh or POPs, as far as you know were available to the FDA in 2001?

A. That's my understanding.

Q. And did you also know that although the POPs study wasn't done, and in fact, didn't get published until 2003, that at a meeting in September of 2001, the POPs study was discussed, the results were discussed, the interim results were discussed between Pfizer and the FDA?

A. No, I didn't know that.

(Discussion off the record.)

Q. Now, for each of these studies -- well, there's something called the primary endpoint, you understand that, correct?

A. Yes.

Q. The primary endpoint is a priori, meaning before the fact, before the results are in there's a defined primary endpoint

which is the primary thing that the investigators are trying to study, correct?

A. Correct.

Q. There might be secondary endpoints, or, I don't even know, are there third, tertiary endpoints, whatever?

A. Well, just to be accurate, you can have co-primary endpoints. There can be multiple primary endpoints, and then secondary endpoints.

Q. Now, for each of the studies that are here, of course, some of them differ in terms of their primary endpoint, don't they?

A. Yes, I believe so.

Q. All right. And when you gave your analysis, you did not actually report to the jury earlier today what the primary endpoint conclusions were as indicated in the reports for each of these studies, did you?

A. No.

Q. Now, are you aware that the original version of the Gorson -- actually, let me put it, also, you indicated that you did not include Gorson in your study because it was measuring something different than what you wanted to look at, correct?

A. What I wanted to look at --

Q. Yes or no?

A. -- and what Dr. Perry looked at.

Q. So you did not include Gorson, correct?

A. No, I couldn't have.
Q. Okay. Nevertheless, are you aware that at least the original report of Gorson indicated that gabapentin is probably no more effective than a placebo? Are you aware of that?
A. No.
Q. And even though -- that's a double-blind, randomized, controlled trial, correct?
A. Correct.
Q. And so although it's a double-blind, randomized, controlled trial that comes to the conclusion that Neurontin is no better than a placebo, you haven't even included that in your analysis in terms of the conclusion you've given to this jury that Neurontin is terrific, or good, for neuropathic pain as a whole, have you?
A. My --
Q. Yes or no. Have you included Gorson?
A. Not in my reanalysis, no.
Q. Are you aware that the results of the POPs study, in terms of the primary endpoint -- not some other thing, but the primary endpoint -- was that Neurontin does not affect for post-surgical or traumatic neuropathic pain?
A. No.
Q. Are you aware that the conclusion as indicated in Serpell was that Serpell did not support a broad neuropathic pain claim because the benefit was limited to shingles patients, which

were 14 percent, and to a very small, i.e., two percentage of patients, for PDM?

MR. HOOPER: Objection, your Honor.

THE COURT: Overruled.

A. No.

Q. In terms of the Reckless study, are you aware that in terms of the primary endpoint there was no statistically significant difference between any of the gabapentin groups and the placebo group for endpoint mean pain score for any time throughout the trial?

A. I'd have to go back to the study to verify that.

Q. Now, you showed the jury a slide 14, the defendant's slide 14.

MR. SOBOL: Switch, please.

Q. Do you recall having given some testimony about this?

A. Yes.

Q. Now, isn't it fair to say that the bars that you have on this chart are actually things that you calculated, correct?

A. Correct.

Q. These aren't things that the original authors calculated, is it?

A. In some cases they may have, but these are my calculations.

Q. Right. And so this notion of an odds ratio, or whatever, is not the primary endpoint as indicated in any of these

studies, is it?
A. Not necessarily, no.
MR. SOBOL: Let's take that off.
A. Can I make one statement about this?
Q. Let's go to slide 17.
You showed to the jury this slide which purported to be a benefit-to-risk ratio using Dr. Perry's calculations. Do you recall that?
A. That's correct.
Q. Okay. And when you used the risk on the right-hand side, you're actually measuring not all adverse events, are you?
A. No.
Q. You're only measuring those adverse events which were so much that the person actually had to get out of the study, right?
A. The patient decided to drop out of the study, that's correct.
Q. Now, if -- and so, actually, if one looked at it, the adverse events' bar on this chart would be much larger if one wanted to include all adverse events, wouldn't it?
A. Yes, it would.
MR. SOBOL: Let's go to the defendant's slide 22.
Q. Now, you also gave some testimony -- this was what you said were the results of this synthesized effort because you were able to get the underlying data and perform an analysis,

correct?
A. Correct.
Q. And this, again -- this analysis, like your other analysis, includes not only GPN but also shingles studies as well, correct?
A. Correct.
Q. You did not back out the shingles studies for this, correct?
A. I did it the same way Dr. Perry did it.
Q. Well, you're also aware, by the way, there are some analyses that Dr. Perry did where he actually did back out the shingles studies. Do you recall something to that effect in his report?
A. Not off the top of my head, but it may have been there.
Q. Now, looking at slide 22 -- so, first, this has the synthesized studies, number one, and then -- then you depict these, correct? Right?
MR. SOBOL: If we could go to the Elmo, actually, for a moment. Sorry to jump around on you here.
Q. I wanted to make an observation, if I can apologize for my pigeon scratch here about.
First, if you look at the first three weeks on this chart -- do you see the first three weeks?
A. Yes.
Q. And actually, if you look to the right, after the first

three weeks, isn't it fair to say that generally the placebo line and the Neurontin line, even for the synthesized studies that include the shingles studies, starts levelling off together?

A. That's correct.

Q. Okay. There seems to be some phenomenon, although it's about one point on the pain scale, but there's some phenomenon going on here in these subjective studies that have a potential for unblinding that's going on in the first three weeks; isn't that fair to say?

A. I don't understand your question.

Q. Do you agree that a pharmaceutical company has a paramount responsibility to tell the truth about a drug that it is selling to the American public?

A. I'm not an expert on what pharmaceutical companies should and should not do. I think we all have an obligation to be as honest as possible.

Q. Well, and don't you think that a drug company should be honest and tell the truth about its products that people -- that it's selling to the American public?

MR. HOOPER: Objection.

THE COURT: Overruled.

A. Yes.

Q. And how about telling the truth, the whole truth, and nothing but the truth?

A. Yes.
Q. And wouldn't you agree that one of the reasons for that is because the dollars to a drug company are simply not as important as the health and safety of Americans?
MR. HOOPER: Objection.
THE COURT: Sustained, argumentative.
BY MR. SOBOL:
Q. Let me ask it this way, then.
If a company were to not tell the truth about its products and a customer does not get what it thinks it's getting, do you think that drug company should be held accountable?
MR. HOOPER: Objection.
A. I'm a statistician. I'm not sure I'm in a position to answer those questions.
Q. Have you heard the term "snake oil"?
A. Yes.
Q. Snake oil is -- generally can mean a product that's sort of bogus and not what it really is supposed to be, right?
A. Correct.
MR. SOBOL: Why don't we go to Plaintiff's Exhibit 479, which is in evidence.
Can you yellow highlight from "gabapentin" and "studied"?
Q. Now, sir, I've put up on the screen what's been marked in

evidence as Exhibit 479, which is an e-mail written by a Pfizer employee. It says, "Gabapentin is the 'snake oil' of the twentieth century. It has been reported to be successful in just about everything that they have studied."

Were you told that some people, or at least one person, in Pfizer in 1999 thought that gabapentin was the snake oil of the 20th century?

A. No. I saw this last night. I'm not sure this person was a Pfizer employee when he said this.

Q. He was.

Well, let me ask this. Today you have come into this court and you have told this jury that Neurontin is effective for a broad range of neuropathic pain, and you've also told this jury that Professor Jewell, Dr. Perry, and Dr. McCrory are all wrong, correct?

A. I wouldn't necessarily say I've said they were all wrong.

I believe Dr. McCrory and I came up with very similar findings based on the analysis of those three studies. I think Dr. Perry made some mistakes, but identified effects that were statistically significant and consistent across the studies. I verified those, found similar results.

And Dr. Jewell tried to explain the results of Backonja using an unblinding hypothesis that I believe does not fit the data whatsoever. So I definitely disagree with him in that regard, but he and I also performed analyses of the

original Backonja article that produced very similar statistically significant findings.

Q. And so let me ask you then, if you knew at the time that Pfizer first came to you and said, We want you to come to an opinion about these gentlemen's reports but at that time you also knew that Pfizer insiders called Neurontin snake oil, would you sill have accepted the job?

MR. HOOPER: Objection, your Honor?

BY MR. SOBOL:

Q. Yes or no?

THE COURT: Overruled.

A. Yes.

MR. SOBOL: Nothing further, your Honor.

MR. HOOPER: I'll say right here, your Honor, two minutes.

First put up slide 14, our slide 14.

REDIRECT EXAMINATION

BY MR. HOOPER:

Q. Dr. Gibbons, recall earlier this morning we showed the jury the results of your analysis in this format?

A. Yes, I do.

Q. When Mr. Sobol just questioned you, he asked you whether you disclosed to the jury that your studies were for different indications.

Would you look across the bottom row of the chart that

we showed the jury and tell the jury what those acronyms and the word "mixed NEP" means on the slide?

A. They describe the study indications diabetic peripheral neuropathy and the other one, PHN. So, in fact, that was disclosed in my testimony.

Q. POPP under Gordh is postoperative pain?

A. Yes.

Q. And mixed NEP is mixed neuropathic pain?

THE COURT: What is mixed neuropathic pain?

MR. HOOPER: A variety of different pain conditions. Sorry.

MR. SOBOL: Let's put Mr. Hooper on the stand.

MR. HOOPER: I'd be happy to.

THE COURT: I think we all get MDs, honorary, anyway. What was the NEP, again?

THE WITNESS: Mixed indications, different kinds of pain.

BY MR. HOOPER:

Q. By the way, this smooshing or synthesizing or combining of data, is that exactly the same thing that Kaiser's expert, Dr. Perry, did?

A. Yes, it is.

Q. And wasn't that the whole point, to try to match what he did?

A. Absolutely.

MR. HOOPER: Okay. Now, can we bring up -- can you bring up your 479 again? It is the last slide that you just showed.

This document about -- from 1999 about gabapentin, snake oil, et cetera.

Can we look at the bottom of that document and blow up the bottom paragraph, beginning with the "Hi, Geoff," and the quote right below it, down to about right there. That's fine.

Q. Do you see there that somebody there named Amanda is writing to somebody named Geoff and says, "A new study has shown that Warner-Lambert's convulsant gabapentin can significantly reduce symptoms of social phobia but the company is not planning to develop gabapentin for this indication because the U.S. patent expires next year."

Do you see that?

A. Yes.

Q. Do you notice that it doesn't say a study that our anticonvulsant gabapentin, does that?

A. I did notice that.

Q. Do you understand this is before the merger and Pfizer was actually a competitor of Warner-Lambert at this time?

A. That was the basis of my statement that this person did not -- it was my understanding did not work for Pfizer, it was a competitor.

Q. And they're reacting to a positive study?

A. Correct.

Q. About a competitor's product.

All right. You were asked about a letter you wrote -- well, first you were asked about a bill that you sent that mentioned a bipolar cohort in August 2008, and then a letter that you wrote in March 2009 about eight months later. And the bill mentions a bipolar cohort, and the letter, eight months later, mentions a bipolar cohort which forms the basis of the paper you're currently reviewing.

Same cohorts?

A. No.

Q. What was the difference between the two and why is it that the one in the invoice isn't the one in the letter?

A. The one in the invoice was from the original data set that I had gotten from the PharMetrics company.

Q. And what is that?

A. That is a database of 131,000 patients who were treated with gabapentin.

Q. Is that a national sample?

A. It's a national sample of over 50 million lives covered and nationally representative.

Q. And why couldn't you use the cohort in the invoice in the paper nine months later?

A. Because only 2.9 percent of the 131,000 patients who were treated with gabapentin had a diagnosis of bipolar. And of

those 2.9 percent, 70 percent of them also had a diagnosis for pain. So it wasn't relevant to the case for which that study was being conducted.

MR. HOOPER: Nothing further, your Honor.

MR. SOBOL: Nothing further, your Honor.

THE COURT: Thank you.

Now, again, we have another doctor here, so we still have maybe 15 minutes of Dr. Glanzman remember from the deposition, but just because I'm trying to accommodate these doctors' schedules, if it's possible to get them on and off, I'm not sure now, I'd like to try to it.

Is Dr. Rothschild here?

MR. HOOPER: Yes, your Honor. Pfizer calls Dr. Anthony Rothschild. We're ready to proceed.

ANTHONY ROTHSCHILD, having been duly sworn by the Clerk, was examined and testified as follows:

THE CLERK: Thank you. You may be seated. And would you please state your name and spell it for the record.

THE WITNESS: Dr. Anthony Rothschild, R-o-t-h-s-c-h-i-l-d.

DIRECT EXAMINATION

BY MR. HOOPER:

Q. Dr. Rothschild, what is your profession?

A. I'm a psychiatrist.

(Discussion off the record.)

MR. HOOPER: Mr. Alba, can you switch us again?

Q. Doctor, as a psychiatrist, where do you work?

A. I'm a professor of psychiatry at the University of Massachusetts Medical School in Worcester, Massachusetts.

Q. Where did you get your medical training, sir?

A. After graduating from Princeton I went to medical school at the University of Pennsylvania School of Medicine in Philadelphia, and then I came up to Boston and did my internship at Mass. General Hospital and Mt. Auburn Hospital in medicine and neurology and then my psychiatry residency at McLean Hospital in Belmont, Mass.

Q. Are you certified in any medical specialty?

A. Psychiatry.

Q. How long have you taught psychiatry in medical schools?

A. Well, after finishing my residency at McLean I went on the faculty of Harvard Medical School, so that's 1983, and I taught medical students and residents at Harvard; and then in 1996 moved to University of Massachusetts Medical School, and I've been doing that there as well.

Q. And while you were teaching at Harvard were you a director of psychopharmacology at McLean Hospital?

A. I was the associate director, yes.

Q. What does psychopharmacology refer to?

A. Simply that's the use of medications to treat psychiatric illness.

Q. And while at Harvard Medical School were you also the clinical director of the mood, anxiety and trauma disorders program?

A. Yes.

Q. What does that mean?

A. Well, actually, I started out as a psychiatrist in charge of the depression treatment and research unit, and then in 1988 I was promoted to this position. Basically I supervise several inpatient units, an outpatient program, a partial hospital program that treated mood, anxiety and trauma, PTSD.

Q. Briefly, what are mood disorders?

A. Mood disorders would be including unipolar depression, where people just suffer from depression; as well as bipolar disorder, where people have depressive and manic episodes.

Q. And briefly, what are anxiety disorders?

A. Includes a number of things, general anxiety disorder, panic disorder, social phobia order, obsessive-compulsive disorder.

Q. Can a patient's clinical presentation, their problem, include both mood and anxiety disorders at the same time?

A. Yes. Actually, that's fairly common.

Q. Did you move to the University of Massachusetts Medical School about 14 years ago?

A. Yeah, in July of 1996.

Q. What is your position at UMass Medical School today?

A. I have an endowed chair. I'm very fortunate to have the Brudnick endowed chair in psychiatry and I'm also director of the Center For Psychopharmacological Research and Treatment and I also have had other positions there as well.

Q. What are some of the other positions you've had at UMass?

A. I was director of clinical research, also vice chair for research. I also direct the Senior Scholars Program, which is a program for medical students who want to get into research.

Q. Are you pretty familiar, Doctor, with the way that scientists study potential new treatments for psychiatry problems?

A. Yes.

Q. Are you familiar with the way that clinical trials of medications are designed, for example, randomized, double-blinding?

A. Yes. I've been an investigator on many clinical trials. I've also designed clinical trials.

Q. When you train new psychiatrists at UMass, do you teach the students how to interpret the various kinds of clinical trials and studies and apply that to their practice?

A. Yes. Actually, I'm a co-director of a course for third-year residents where that's the whole purpose of the course. We take articles from the literature and we review them and critically review them and then ask the basic question that many of these psychiatrists who -- they're going into

practice, they're not going to be working at a university -- how do you, after you graduate, read the literature and apply it to your practice?

Q. Are you generally familiar with the FDA approval process, evaluating the safety and efficacy of new medications, just in general?

MR. GREENE: Objection, your Honor.

THE COURT: Overruled.

A. Yes, I am.

Q. Before we get to your own publication experience, Dr. Rothschild, let me ask you, were you present here in the courtroom early on during the first three days of the trial?

A. Yes.

Q. Did you hear the testimony of Kaiser's witnesses, Drs. Abramson, Dickersin, and Barkin?

A. Yes.

Q. Did you also see Dr. Furberg's testimony the other day?

A. Yes, I did.

Q. Had you read their expert reports even before you heard their testimony in the courtroom?

A. Yes.

Q. When were their reports dated, and when did you get a copy?

A. I think they were dated sometime in the middle of 2008, and I think I received them probably towards the end of 2008.

Q. Had you read Dr. Dickersin's article in the New England Journal of Medicine that came out last November before he started testifying?

MR. GREENE: Objection, your Honor.

THE COURT: Sustained.

BY MR. HOOPER:

Q. Are you generally familiar with what the Kaiser witnesses had to say during the course of this trial about Neurontin?

A. Yes.

Q. How many articles have you published in peer-reviewed journals?

A. Probably over a hundred.

Q. Are you yourself a peer-reviewer for medical and scientific journals?

A. Yes.

Q. Which ones?

A. Well, quite a -- I'll list a couple. American Journal of Psychiatry, the New England Journal of Medicine, Archives of General Psychiatry, and -- you know, more than 17.

Q. Do you stay current on the medical and scientific literature about treating psychiatric problems with medication?

A. That's actually part of my job, yes.

Q. Did your assignment in this case include evaluating the reports of two Kaiser experts, Dr. Barkin and Dr. Furberg?

A. Yes, it was.
Q. And were you asked to evaluate their claims that Neurontin increases what they call depression with or without suicide ideation?
A. That's correct.
Q. Were you also asked to evaluate their claims that information about depression and suicidality wasn't properly disclosed?
A. Yes, I was.
Q. Would you please state the sources of information that you used to develop your opinions in this case on this question?
A. Well, there were a couple of sources. I looked at the results that were published, double-blind, randomized, controlled clinical trials, DBRCTs, that use validated rating scales for depression. I looked at the Neurontin --
Q. Let me stop you right there, Doctor, for a second. When you say a validated clinical rating instrument for depression. Can you explain to those of us who aren't familiar, what are you talking about there?
A. Well, the thing is, when you do research in psychiatry, it's different, say, from putting a chest x-ray up and saying there's the lesion. We have standardized rating scales that researchers use to assess the degree of depression. So examples of that, for example, would be the Hamilton depression rating scale, or the MMPI; there's a couple of them.

Q. And are those questionnaires, in effect, that ask a series of questions about a patient's depression?

A. Well, yes. There are specific questions that are asked and then, depending on what the answer of a person is, there are what are called anchors to give them a score based on what they say. And it's even a little more complicated than that, there's sometimes follow-up questions.

Q. Are those rating instruments, is that something instead of having an x-ray taken do you have the Hamilton-D administered regularly during a trial?

A. Well, yes. You might do them every week, sometimes it could be every two weeks. It's -- it could be every month. But, yes, you would administer them on a regular basis throughout the study.

THE COURT: So like what kind of questions?

THE WITNESS: Well, item number one is mood, which is, are you depressed? Item number three asks about suicidal thinking. Do you have any thoughts? Do you have any plans? There are questions on there about energy level, sleep. There's actually three questions on sleep. I'm referring to the Hamilton depression rating scale. There's questions about --

THE COURT: So is it yes/no or is it a scale of --

THE WITNESS: No, no, it's a scale from zero to three and some items four.

BY MR. HOOPER:

Q. And depending on which version you use, there are about 23 to 29 questions on the different scales, correct?

A. Some have 17 -- when I say it's standardized, for example, what's considered normal mood, not depressed, would be a score of, say, 8 or less.

So when you treat a person and you want to get them into remission, you make them no different than somebody who is not depressed, that would be a Hamilton score less than 8. Above 30 is severe depression. Eighteen up to 25, that's moderate depression.

Q. Other than beyond the DBRCTs that use those kind of scales, what other information did you use to form your opinions in this case, Doctor?

A. Well, I also looked at the Neurontin controlled clinical trial data, including the FDA review of 2002, as well as the FDA statistical review regarding antiepileptic medications and suicidality in 2008. I looked at the labelling and the FDA approval letters from 1993 and then in 2002. And then -- I've been doing this for a while, so I also base it on my professional training and my clinical experience, including prescribing Neurontin.

MR. HOOPER: Can we turn to slide 5?

Q. Doctor, would you please give the jury a summary of your opinions before we get into the details?

A. Sure. My opinions are that there's no reliable scientific evidence that shows that the use of Neurontin causes or worsens depression with or without suicidal ideation. And that the controlled data consistently finds no such effect. And that would include published controlled studies in the medical literature that systematically evaluated whether -- for depression via validated clinical rating instruments. And in the Neurontin placebo-controlled trial clinical data. And then, finally, the Neurontin United States Professional Package Insert explaining the available data on depression and suicidality.

Q. Before we turn to the studies and data, let's start with your clinical experience.

First, is your clinical practice specialized, focused in psychiatry?

A. Yes.

Q. Do you use Neurontin to treat some of your own patients?

A. Yes.

Q. What kinds of patients are you using Neurontin to treat?

A. Well, I prescribe it for people who suffer from anxiety symptoms, anxiety disorders, social phobia. I have a number of patients with bipolar disorder who also have symptoms of anxiety or social phobia. And then I've got other patients in my practice who are on Neurontin from other doctors.

Q. How many patients with bipolar disorders are you using

Neurontin to help treat, treat or help treat?

THE COURT: Can we just refine that? Solely with bipolar, not with the others.

THE WITNESS: I'm not sure I understand the question. You mean not the ones getting it from other doctors?

THE COURT: No. They have also social phobias and anxiety.

THE WITNESS: Okay.

A. Ten to 15.

Q. Doctor, about how many patients with bipolar disorders all total are you treating with Neurontin at this time?

A. Thirty to 40.

Q. And is that number fairly consistent, the numbers of bipolar patients that you've treated with Neurontin, say, over the past decade?

MR. GREENE: Objection, your Honor.

THE COURT: Overruled.

A. Yeah, it's stayed fairly constant.

Q. What portion of your bipolar patients are taking only a single medication, like a mood stabilizer like lithium or Depakote?

A. I'd say about half. Half are on just one medication, the other half would be on more than one.

Q. On multiple medications?

A. Yes.

Q. Again, are some of the patients you see for psychiatric problems also being treated by other doctors for other non-psychiatric problems?

A. Yes.

Q. And are some of those -- do you have some patients who you are seeing who are prescribed -- who come to you with a prescription for Neurontin that they got from a different doctor for a non-psychiatric problem as well?

A. Yes. And that -- you know, most commonly would be either from the pain clinic or from their primary care physician. It's usually for pain.

Q. Have you read the U.S. Professional Package Insert or labelling, the thing that appears in the Physician's Desk Reference?

A. Yes.

Q. And various times over your career you've seen that?

A. Yes.

Q. And the package insert or labelling has lots of information about warnings and precautions and adverse reactions and that sort of thing in it, correct?

A. Yes.

Q. How does your clinical experience in your own Neurontin patients match up with what you've seen in the labelling in the PDR?

A. It's completely consistent with it.

MR. HOOPER: Let's go to slide 6.

Q. Let's turn now to the DBRCTs with the depression rating scales that you looked at.

MR. HOOPER: Slide 7.

Q. Can you briefly explain the Guille study and its significance to your opinion about Neurontin and depression?

A. Okay. So this was a study actually done in Boston at Mass. General, was adjunctive treatment for refractory mania. In that study they used the Hamilton depression rating scale, which I had discussed briefly earlier, and what they found was that there was no difference on the Hamilton scores between those people who got Neurontin and those people who got placebo, which goes against any argument that Neurontin makes depression worse, because there was no difference.

In fact, actually, there was a suggestion at the fifth week that Neurontin actually improved depression compared to placebo, and that was statistically significant, less than .05.

Q. Let's get a couple of terms straight. What's adjunctive treatment?

A. Add-on.

Q. And what does "refractory" mean?

A. These are people who have had the usual treatments and didn't get better. Probably failure on a couple of previous treatments.

MR. HOOPER: Slide 8, please.

Q. The jury has heard about the Frye study. What patients did Dr. Frye study, if you could remind us?

A. Well, Mark Frye studied refractory bipolar one patients, bipolar two patients, and actually, he also included unipolar depressed people, these are people who just suffer from depression.

Q. Did he also use the Hamilton --

A. Yes, I was going to say he used the Hamilton depression rating scale. And he reported no statistically significant difference between those people who got gabapentin, Neurontin, and those people who got placebo in depression. Again, consistent with the Guille study that there's no worsening of depression with Neurontin.

Q. Now, let's go to the study that we've -- the three Pande studies.

What did -- this is the Pande 2000 gabapentin and bipolar disorder. Can you briefly remind the jury of what Dr. Pande studied and how the drug was used?

A. Right. So this was an injunctive treatment, so an add-on treatment, to lithium, valproate, or in combination. Pande used the Hamilton depression rating scale to access depression, and there was no difference between those people who received Neurontin and those people who received depression on the Hamilton scores. Again, consistent with the other studies.

MR. HOOPER: Slide 10.

Q. Let's turn to Pande social phobia study.

Could you briefly describe this one and how it fits with your opinion?

A. So this was a study of gabapentin versus placebo, again, social phobia. Again, Pande used the Hamilton depression rating scale to assess depression. And at the end of the study there was no difference in Hamilton depression scores between people who received Neurontin and people who received placebo. Again, another piece of evidence that Neurontin does not worsen depression.

MR. HOOPER: And slide 11.

Q. Let's turn on slide 11, Doctor. You'll recognize the Pande panic disorder study.

A. It's --

Q. Did this one also use the Hamilton depression rating scale?

A. Yes.

Q. Okay. And what result?

A. Again, a different type of anxiety disorder, but the same result: No difference in Hamilton scores between those people who received Neurontin and those people who received placebo. Again, no increase, no evidence for worsening depression in people who received Neurontin.

MR. HOOPER: Slide 12, please.

Q. Let's turn to the Vieta study, published in 2006. Was

this also a DBRCT?
A. Yes, it was.
Q. Did this also use the Hamilton depression rating scale on a regular basis?
A. Yes.
Q. And how long was this study?
A. It was a year.
Q. And what type of study was it?
A. Well, it was a prophylaxis. So, in other words, what Vieta did is they took people who were well or in remission from their bipolar disorder, and then looked at prevention of episodes over the course of a year with adding Neurontin or adding placebo.
Q. Is bipolar disorder a disease that over a person's life comes and goes?
A. Yes.
Q. And what were the results on the Hamilton depression rating scale?
A. Similar to the other studies, studies using the Hamilton depress rating score, there was no difference in Hamilton scores between those people who received Neurontin compared those who received placebo.

Now, this one is over the course of a year. So, again, another piece of evidence that there's no worsening of depression with Neurontin.

Q. All right. Let's turn to the next slide.

MR. HOOPER: And, your Honor, I move to admit Exhibit 2004. It's a copy of a study, the first author named Mokhber, M-o-k-h-b-e-r.

(Exhibit 2004 received into evidence.)

Q. What's on the screen is a study by first author Mokhber. Are you familiar with this study?

A. Yes.

Q. Are you familiar with the institution or university that two of the authors on the Mokhber study, Carol Lane and Allan H. Young, come from?

A. Yes, they come from the University of British Columbia.

Q. The same place that Dr. Perry, Kaiser's expert, comes from; is that right?

A. Yeah.

Q. And the remaining authors are from Mashhad University Medical School in Iran; is that right?

A. Yes.

Q. And can you explain what kind of -- first, was this a DBRCT as well?

A. Yes.

Q. And what kind of -- can you explain what kind of disorder the Mokhber study looked at?

A. It was looking at dysphoric mania, which is a type of bipolar disorder, sometimes also referred to as mixed mania.

Plain English, these are people who have, during the course of a day, have both episodes of depression and mania during the course of a 24-hour period.

Q. What was the control in this study?

A. I'm not sure what you mean by control. It was -- I'm sorry. It was a comparison, and the controls were lamotrigine and carbamazepine, two what are called active controls.

Q. As a researcher, are you familiar with something that Dr. Kessler told us about on the second day of trial, adequate well-controlled trials?

A. Yes.

Q. That's the regulatory term that FDA uses?

A. Yes.

Q. And is an active control as well as a placebo control something that qualifies a study as an adequate well-controlled trial?

A. Yes. If you look at the regulations, both are considered adequate control trials. Both types.

Q. Is there any significance, special significance -- well, let me rephrase that.

Is there any particular utility to using an active control as opposed to placebo control in patients with bipolar disorder?

A. Yes. I mean, there's several reasons. One is, when you're dealing with a serious illness like bipolar disorder,

it's sometimes not practical, some would argue not ethical, to give them a sugar pill. There's other examples of that in medicine. That's one of the reasons why you might do an active control study. The other thing is, you know, if I go back to work this afternoon, I mean, doctors -- it's nice for them to know that a drug is better than a sugar pill, but they'll say to you, I'm not prescribing sugar pills. Tell me if it's better than that other thing. That's what this kind of study does.

Q. Did the Mokhber authors address depression in their study with a rating instrument as well?

A. Yes.

Q. And how did they assess depression?

A. They used the MMPI.

Q. Can you explain to the jury what the MMPI II is?

A. The MMPI is the Minnesota Multiphasic -- I can't remember what the I -- Inventory. It's been around for a long time, it's well standardized. It's well -- if you look in the literature search, a lot of people use it for depression studies. It's a validated scale.

Q. They're using it for the same purpose the other studies were using the Ham-D scale for?

A. Yes. I mean, the reason they use it, I think, is because the MMPI has a more cross-cultural sensitivity. They were doing the study in Iran.

Q. The right scale for this locale?
A. Yes, it's a validated scale.
Q. And can you explain the depression results in the Mokhber study and how they relate to your opinions in this case?
A. What they found was -- they found that all three medicines worked. What they found was that Neurontin, gabapentin, showed the greatest change in depressive symptoms compared to lamotrigine and also compared to carbamazepine. And that was statistically significant in that randomized control, double-blind study.
Q. Let's turn now to -- from the individual studies that you looked at, the ones that assess depression using these scales, to the larger bodies of control data that you told us about.
(Discussion off the record.)
MR. HOOPER: I'm going to move to admit Exhibit 642.
THE CLERK: Got it.
MR. HOOPER: This is the 2002 FDA clinical review data.
(Exhibit 642 received into evidence.)
BY MR. HOOPER:
Q. Doctor, were you here when we were discussing this document with Dr. Furberg?
A. Yes, I was.
Q. And, Doctor, if I could ask you to turn to page 77, table 7.20 from the FDA's 2002 clinical review of Neurontin -- of the

Neurontin data. Could you just explain -- remind the jury of what this table shows?

A. Well, it's a long list, a table of treatment emergent side effects or AEs, adverse events, in patients in the neuropathy and epilepsy add-on studies. And depression is one of the things that, obviously, we've been talking about.

Q. And the numbers on the left for all neuropathy studies, 1.3, is that 1.3 percent?

A. Yes.

Q. And then for just the PHN studies alone, it's 0.6 percent?

A. Yes.

Q. And then for the neuropathy trials on placebo, that's 2.2 percent; is that right?

A. Yes.

Q. And then when you get over to the two right columns, now we're in the epilepsy trials with 1.8 percent and 1.1 percent; is that right?

A. Yes.

MR. HOOPER: And then go to slide 16.

Q. Can you explain, Doctor, what this chart shows and how it relates to your opinions?

A. Well, I just have the epilepsy -- the epilepsy studies, the neuropathy studies, and then I combine them, weighting them for the number of patients together. You can see that combined there's really no difference. 1.5 percent rate on Neurontin,

1.7 percent rate on placebo.

Q. Are those -- are there any statistically significant differences in those numbers at all?

A. No, actually none of them are.

Q. And did you hear Dr. Furberg say the left-most two numbers, 1.8 and 1.1, were signalling a 64 percent increase in depression on Neurontin?

A. I heard that.

Q. What was your reaction to that?

A. Well, the point is, is that it's not statistically significant. I mean, that would be like arguing over here the 2.2 versus 1.3 percent in neuropathy studies is meaningful; it is not, it is not statistically meaningful. There is no difference in the rates of depression between placebo and Neurontin in any of these three bar graphs.

MR. HOOPER: Your Honor, this refers to the FDA's statistical analysis and review from two years ago, 2008 pooled analysis, which is already in evidence as Plaintiff's 401.

Q. Doctor, do you recall in your report at page 18 you have a paragraph or two where you discuss a report that was issued by FDA 2008 describing a pooled analysis of suicidality data, suicide ideation, attempts or acts, for 11 different AEDs, one of which was gabapentin?

A. Yes.

Q. First, what is a pooled analysis?

A. Well, it's a grouping. Taking, in this case, 11 different medications and analyzing them as a pool, as a group.

Q. Do you come up with an overall result for the whole pool in a pooled analysis? Is that --

A. That's right. It's an overall result of the entire group.

Q. And do the results of a pooled analysis prove that every medication in the pool has the same effect that is the overall result?

A. No. I mean, this is like -- this is like asking what the batting average of Kevin Youkillis is and then going to the entire Boston Red Sox team average and saying that tells you what Youkillis' batting average is.

I mean, Youkillis, actually, last year hit over .300. The Red Sox batting average was .270. If you wanted to know what Kevin Youkillis' batting average was, you'd look up Kevin Youkillis.

Consequently here, if you want to know what the rate is on Neurontin, you look at Neurontin.

(Discussion off the record.)

Q. I've just enlarged -- or this chart shows the enlargement from the preceding page.

Can you explain to the jury what the gabapentin data means on this chart?

A. A couple of things I would point out. First of all, the number of events on Neurontin is very low. It's two out of

2,900 something. The other thing is it's not statistically significant. I mean, the confidence -- the 95 percent confidence interval crosses one, and therefore, it is not statistically significant.

Q. If you look at the blue bars, is that indicated in any way by the blue bar crossing the --

A. That's just a picture way of saying the same thing. So here's one down the middle, and you can see that the Neurontin gabapentin line crosses through one.

MR. HOOPER: Slide 19, please.

Q. And, Doctor, you brought this chart with two other AEDs, lamotrigine and topiramate, highlight from the same chart we just looked at. Why are they highlighted?

A. Well, they're highlighted because these two are statistically significant. You can see that the blue lines don't cross one. The confidence interval for both lamotrigine and topiramate, their confidence interval does not include one.

You can also see the number of events, there's 27 events on lamotrigine, 40 events on the topiramate. If you think -- put this back into my Boston Red Sox analogy, the batting average of the Boston Red Sox is .270, but it's driven, not by Jason Varitek, who was hitting, I don't know, .200 or something; it's driven by Youkillis, Pedoria, and Ellsbury.

This statistical finding that the FDA did is driven by two drugs, lamotrigine and topiramate, and it's statistically

significant for those two.

(Discussion off the record.)

Q. Bottom line, Doctor, what is your opinion as to whether there is a relationship between Neurontin and increased risk of depression and suicidality?

A. It's my opinion that there's no reliable scientific evidence that shows that the use of Neurontin causes or worsens depression with or without suicidal ideation, and that the controlled data consistently finds no such effect. This would include the published controlled studies that used standardized rating instruments to evaluate depression. It includes the Neurontin placebo-controlled clinical trial data, and it's also my opinion that the Neurontin package insert explains the available data on depression and suicidality.

Q. And, Doctor, do you hold those opinions to a reasonable degree of scientific certainty?

A. I do.

MR. HOOPER: Pass the witness.

CROSS-EXAMINATION

BY MR. GREENE:

Q. Good morning, Doctor.

A. Good morning.

Q. We haven't met before, have we?

A. No.

Q. I just want to ask you a couple of questions.

I saw a slide up there about your assignment. You weren't asked to review any of Pfizer's marketing materials to see or determine or give an opinion to Pfizer whether they had told the truth about Neurontin in the marketing materials. That's not what you are here for today, correct?

A. I was not asked to review marketing materials.

Q. That's a subject we have to get another witness to testify about if we wanted to ask questions about Pfizer's marketing materials, correct?

A. I'm not sure I understand the question.

Q. Well, you're not here to talk about what Pfizer said in their marketing materials to the medical community, are you?

A. I am a member of the medical community.

Q. Will you listen to my question, Doctor?

You're not here to testify --

MR. HOOPER: Objection.

THE COURT: Yes, yes. You need to answer his questions, so listen carefully.

BY MR. GREENE:

Q. You're not here to testify about what Pfizer said in their marketing materials to the medical community, are you?

A. No.

Q. You're Pfizer's expert in another part of the Neurontin litigation, aren't you?

A. Yes.

Q. You've been an expert for drug companies on the suicide issue, a number of different drug companies, haven't you?
A. Yes.
Q. You've testified in a number of different cases on behalf of drug companies on this suicide issue, haven't you?
A. Yes.
Q. You've taken a lot of money from drug companies, haven't you, to give testimony on the suicide issue; isn't that right?
A. Define "a lot," please.
Q. Why don't you tell the jury how much have you been paid by Pfizer for all your work here on Neurontin.
A. Off the top of my head I can only tell you about this particular case, it's probably about 50 hours.
Q. When you say this case, the case you're testifying here today?
A. Yes.
Q. All right. But the bulk of your work has been in the Neurontin suicide cases. That's where Pfizer has paid you, correct?
MR. HOOPER: Objection, your Honor.
THE COURT: As you know, this is what's called multidistrict litigation. You may have wondered why is this here? So they went with the first drawn case and they brought all the cases into this district. So there are lots of cases, and so I think what he's asking about is some of the other

cases.

So did you -- were you an expert in some of the other cases?

THE WITNESS: Yes, I was.

BY MR. GREENE:

Q. That's what I want to ask. Will you tell the jury how much you've been paid in that Neurontin litigation by Pfizer?

A. I don't know off the top of my head, but I can probably give you an estimate. It was a case that started with a B that --

Q. Just looking for an estimate. Can you just give us a ballpark figure? Is it more than $100,000? That's all I want to know.

A. I'd say over the past couple of years it's probably around that.

Q. For all the Neurontin suicide litigation that you've given opinions in it's about a hundred thousand?

MR. HOOPER: Objection, asked and answered.

BY MR. GREENE:

Q. Is that what your sworn testimony is?

A. That's my estimate, yeah.

Q. You're a member of Pfizer's speaker bureau, aren't you?

A. Not anymore.

Q. How long were you a member of Pfizer's speaker bureau?

A. I spoke --

Q. How long were you, not how many times, just how long? How many years?
A. That's what I'm trying to answer. I spoke about Zoloft, so that would have been -- came out around 1992, probably until about 2000, 2001, somewhere -- ended around there, I think.
Q. Fair amount of your income depends upon money you receive from drug companies; is that correct?
A. No, that's not correct.
Q. Have you taken grants from Takeda?
A. I did a clinical trial for Takeda, yes.
Q. Took a grant from the Takeda company, correct?
A. Yes.
THE COURT: What is that?
BY MR. GREENE:
Q. Is that a drug company?
A. Yes.
THE COURT: Is it a generic, a brand?
THE WITNESS: It's a Japanese company.
BY MR. GREENE:
Q. Took grants from Cyberonics?
A. Yes.
Q. Took drug grants from Merck?
A. Just to clarify --
Q. Just answer my question.
A. Then I'm going to answer no, because the grants don't --

Q. That's fine --
A. -- don't go to me, they go to the university.
THE COURT: I think that is a worthwhile distinction.
So on behalf of the University of Massachusetts, is that --
THE WITNESS: The money goes to the University of Massachusetts Medical School, and then that supports the research.
BY MR. GREENE:
Q. Correct. The research that you're conducting; isn't that right?
A. Yes.
Q. You and your colleagues and your department?
A. My department and other departments, sometimes it's a collaboration.
Q. And my point is that you and your department depend on that grant money from the drug companies, don't you?
A. I don't think that's fair to say. I mean, it's a small fraction of my salary support, for example, comes from pharmaceutical companies.
Q. I didn't ask about your salary. I'm asking about grants that you get for your department. You've got the grants from Merck, Lilly, Forest, AstraZeneca, Bristol-Meyers, and Pfizer; isn't that correct?
A. It sounds like you're reading from a disclosure in the

Archives of General Psychiatry, which requires me to go back ten years. Those include all the grants in the last ten years.

The current funding is from Cyberonics, and that's it.

Q. Doctor, I'm reading a list you gave in a sworn deposition. That's where I got those answers.

A. It's correct, but it goes back over a long period of time.

Q. You say you have a pretty extensive resume' here. You authored a hundred about -- about a hundred articles?

A. Yes.

Q. Did you write those articles?

A. I either wrote the entire article in some cases, or significant portions of them, yes.

Q. You didn't just put your name on the article, did you?

A. No.

Q. The article wasn't ghost written by a medical marketing company?

A. No.

Q. You know what ghostwriting is, don't you?

A. Yes.

Q. You were sitting here last week when Dr. Glanzman's videotaped deposition was played?

A. No.

Q. You did come and hear Dr. Furberg, correct?

A. Yes.

Q. Have you conducted clinical trials?

A. Yes.
Q. And you recognize his book as one of the leading books in the world on clinical trials, don't you?
A. I mean, I heard that testimony. I'm not familiar with it.
Q. You're not familiar with his book?
A. No.
Q. You heard him testify that he had authored 400 peer-reviewed papers?
A. Yes.
Q. You've never given any testimony against a drug company in a civil lawsuit, have you, Doctor?
A. That's not correct.
Q. You have? You've testified on behalf of a plaintiff that's suing a drug company?
A. No. These were two drug companies suing each other.
Q. You'd agree with me that the way you test a drug to see if it's effective is you conduct a randomized, controlled, double-blind study of the pharmaceutical agent versus a sugar pill, to use your words; is that correct?
A. That's right.
Q. And if you wanted to show that a medication was effective, say Neurontin, that's what you'd have to do, a randomized, double-blind, placebo-controlled study, to use your words, correct?
A. That was done with Neurontin.

Q. Pardon me?
A. That was done. If you look at the Mokhber study or the Vieta study --
Q. We're going to get to those. I'm just asking if that's your testimony, your testimony under oath.
A. Yes.
Q. You were here when Dr. Furberg was talking about the combined medical statistical review that the FDA had conducted back in the 1992, 1993 time period when they were looking at the epilepsy clinical trials, right?
A. Yes.
Q. You heard his testimony about that?
That's the subject I'd like to turn to.
MR. GREENE: Can we get Exhibit 207?
Let me give you a copy of that exhibit, Doctor, 207.
(Discussion off the record.)
Q. Can you turn to page 22?
This is the medical statistical review that the FDA conducted looking at the epilepsy trials for adjunctive treatment of refractory partial epilepsy, correct, Doctor?
A. Yes.
Q. It's signed in May and June 1993 by five FDA officials?
A. Maybe I'm on the wrong page. Did you say page 22?
Q. The first page, directing your attention.
A. Oh.

Q. I think we have it up on our screen.
A. Okay.
Q. Does that help you?
A. Yes. You started talking about signatures, I was looking for signatures.
Q. Well, we can turn to page 1 -- see on your screen there, there's the signature page?
A. Right.
Q. This was part of what Dr. Furberg testified about last week, correct?
A. Yes.
Q. And the FDA prepared this document, didn't they?
A. Yes.
Q. Now, could I have you turn to page 31? Excuse me. In your text, 114. Under the heading "Depression, suicidal ideation, suicide attempt." Do you see that?
A. Yes.
Q. This is what the FDA wrote when they did this review, follow along with me, Doctor: "In the total exposed population of the NDA" -- that's the New Drug Act application -- "78 (5.3%) patients reported depression as an adverse event."

Are you following me?

A. Yes.
Q. That's what the FDA wrote, correct?
A. Yes.

Q. "This included one subject in a phase one study. There were several reports of depression as serious adverse events in nine patients who withdrew from studies because of depression." Correct?

A. Yes.

Q. I want to turn your attention now to the next paragraph.

"There is some underrepresentation in certain categories. For example, in some cases depression was reported as a serious adverse event, particularly if it resulted in hospitalization or was associated with suicide ideation." That's what the FDA wrote, correct?

A. Yes.

Q. "However, numerous examples were identified among the CRFs" -- case report forms?

A. Yes.

Q. -- "where a patient developed treatment emergent depression where pharmacological intervention was required and the report of a serious adverse event was not made."

That's what the FDA wrote back in 1992, '93 time period, correct?

A. Yes.

Q. I direct your attention to page 116. "Summary conclusions and recommendations," if we can get that up.

Do you have that in front of you, Doctor?

A. Yes.

Q. "As of the data cutoff date of September 30, 1992, data from clinical trials involving 2,048 subjects indicate that gabapentin has a safety profile that is generally good but about which there remain several important concerns."

Is that what the FDA wrote?

A. Yes.

Q. All right. Let's turn to the next page, 117, the third paragraph down, the sentence that begins with "Less common." Are you there, Doctor?

A. Yes.

Q. "Less common but more serious events may limit the drug's widespread usefulness."

Do you see that?

A. Yes.

Q. All right. The FDA was being asked to approve this drug for adjunctive therapy in treating certain types of seizure, correct?

A. Yes.

Q. They weren't being asked to approve it for bipolar disorder or pain or migraine, correct?

A. I believe that's correct, yeah.

Q. The FDA in that paragraph goes on to mention some of the concerns, don't they?

A. Yes.

Q. All right. Let's drop down to the third concern they

mention. I think it's the fourth sentence in the paragraph. Do you see that? It says, "A third is that depression" -- do you see that sentence?

A. Yes.

Q. Following along with me now. "A third is that depression, while it may not be an infrequent occurrence in the epileptic population, may become worse and require intervention or lead to suicide, as it has resulted in some suicidal attempts."

Again, that's what the FDA wrote in 1992 and 1993, correct?

A. Yes, in 1992 and 1993.

Q. Now turn to the last page there, the one with the signatures. Do you have that there, Doctor?

A. Yes.

Q. They write their recommendations there, right? "In conclusion NDA" -- new drug applications -- "20-235 is approvable with appropriate and prominent labelling for use in a specific population."

Is that what the FDA wrote?

A. That's what they wrote.

Q. And again, the specific population is referring to epilepsy patients -- actually, adult epilepsy patients but for only adjunctive therapy, in combination with another antiseizure drug; is that correct?

A. Yes.

Q. That's what our FDA said back in 1992 and 1993 time period, right?

A. Yes.

(Discussion off the record.)

Q. Now, I want to direct your attention to 1158. You've seen this before, haven't you, Doctor?

A. Yes.

Q. This is authored by the defendant's employees, correct?

A. It was authored by Parke-Davis employees.

Q. Well, you know Atul Pande, right? He was an employee of the defendants?

A. I've never met him but I know him, yes.

Q. And Dimond. Disclosed right here, it says, "CNS clinical research and development, Parke-Davis Pharmaceutical Research, a Division of Warner-Lambert Company," right?

A. Yes.

Q. And it's dated February 1996, right?

A. Yes.

Q. And the defendant's employees entitled this journal article, "Effect of Gabapentin Neurontin on Mood and Well-Being in Patients With Epilepsy," right?

A. Yes.

Q. And the abstract is the summary of the article, right?

A. Usually is, yes.

Q. Let's just look at the abstract. They were looking at the

same data that the FDA was summarizing in the medical statistical review that we just reviewed with the jury, right?

A. Yeah -- yes.

Q. Let's see what the defendant's employee said here.

Number one, did they write: "Global improvement data from five double-blind clinical trials of gabapentin as add-on therapy in patients with epilepsy were reviewed to assess the effects of gabapentin on mood."

Is that what they wrote?

A. Yes.

Q. "Number 2. One hundred ninety four (46 percent) of 423 gabapentin treated patients reported improvements in general well-being as compared with 79 (29 percent) of the 271 placebo-treated patients."

Did they write that?

A. Yes.

Q. And finally, "Finding support anecdotal reports of improved affective status among patients taking gabapentin and suggest that the study of gabapentin in psychiatric populations may be warranted."

Right.

A. Yes.

Q. And you've reviewed that article, correct?

A. Yes.

Q. And nowhere in that abstract do they disclose what the FDA

had pointed out with regard to the increased risk of depression that we just reviewed with the jury?

A. Well --

Q. It's not in the abstract, is it?

A. I just went through in my direct testimony all the studies to show there is no increased risk of depression.

Q. Doctor, can you just listen. I know you're paid by Pfizer, just listen to my question.

MR. HOOPER: Objection.

THE COURT: Sustained. Just rephrase it.

BY MR. GREENE:

Q. Just listen to my question.

When these defendant's employees wrote up in this abstract those three points, did they disclose what the FDA had pointed out that we -- you and I just reviewed with the jury? Is it in those three paragraphs?

A. No.

Q. You'd agree that a drug company should be truthful when they're writing to the medical community about their product, wouldn't you?

A. Look, you make it sound like --

THE COURT: Yes or no.

A. Repeat the question, please.

Q. You'd agree that a drug company, Pfizer, should tell the medical community the truth about their products?

A. Yes.
Q. You'd agree that Pfizer should tell the medical community the truth about Neurontin?
A. Yes.
Q. You'd agree that Pfizer, if they've gotten negative study results, should disclose them to the medical community, shouldn't they?
A. If they can get it published, sure.
Q. And if they can't get them published, is it your testimony that they have no obligation to disclose a negative finding to the medical community?
A. Well, it's very --
Q. Can you answer that yes or no?
A. No --
Q. Can you answer my question yes or no?
A. Please repeat the question.
Q. Is it your testimony that if Pfizer has negative findings about Neurontin and they can't get it published, then they don't have to disclose those negative findings to the medical community?
A. As a member of the medical community --
Q. Can you answer that question yes or no?
MR. HOOPER: He's trying to answer it.
THE COURT: Yes. What's your answer?
A. As a member of the medical community it's important to

have as much information as possible.
Q. Look, you treat patients?
A. Yes, I do.
Q. Don't you want the drug companies to tell you the truth about the drug products so that you can treat your patients?
MR. HOOPER: Objection.
A. I want everyone to tell me the truth, but, you know --
Q. Can you answer my question? My question was limited to drug companies.
Don't you want Pfizer to tell you the truth about Neurontin when you're going to prescribe it for your patients?
A. I do prescribe it.
MR. HOOPER: Objection, your Honor.
THE COURT: No -- right, so -- -- you're still objecting?
MR. HOOPER: I do.
THE COURT: Overruled.
Do you want Pfizer to tell you the truth when you're prescribing to your patients?
THE WITNESS: Yes.
THE COURT: All right.
BY MR. GREENE:
Q. And if Pfizer withheld negative data from you concerning their drug, Neurontin, that could impact the treatment decision you make in prescribing for your patient?

A. I'm not sure I understand what negative data you're referring to.

Q. You didn't look at any of the Pfizer and Parke-Davis neuropathic pain studies, did you?

A. I'm a psychiatrist. I don't prescribe if for neuropathic pain.

Q. I didn't ask you that. Did Pfizer give you any of the neuropathic pain studies?

A. No.

Q. Did they give you any of the negative nociceptive pain studies?

THE COURT: Excuse me.

MR. GREENE: I'll move on.

BY MR. GREENE:

Q. Now, I think one of the points you were trying to make to the jury with those slides that were shown concerning the depressive effects of Neurontin compared to placebo is that there isn't any difference; is that right?

A. There's no difference -- there's no worsening of depression in -- with treatment with Neurontin.

Q. Okay. So I think your point is in looking at those studies that for patients that received Neurontin didn't get any more depressed than the patients that received placebo; is that right?

A. Yes, although in the Vieta and the --

Q. Can you just --
A. -- there was additional benefit.
Q. Can you answer my question?
A. I thought I just did.
Q. The patients didn't get any worse in terms of depressive effects?
MR. HOOPER: Your Honor, can he answer the question? He's stepping on his answer every time.
THE COURT: Well --
MR. GREENE: Well, let me try a new question. I'll withdraw that.
BY MR. GREENE:
Q. Let's take Exhibit 207, please. Excuse me, I said 207, I meant to say Exhibit 401.
A. Is that something I have here?
Q. I think you should have it in your binder, Doctor. 401?
A. Yeah, I have it.
Q. You've seen this exhibit before, correct?
A. Yes.
Q. In fact, you talked a little bit about it on your direct examination, right?
A. Yes.
Q. Now, this is dated -- Statistical Review and Evaluation Antiepileptic Drugs and Suicidality dated May 23, 2008, correct?

A. Yes.

Q. This is our Food and Drug Administration, once again, issuing a report on the antiepileptic -- excuse me, on 11 antiepileptic drugs, correct?

A. Yes.

Q. And Neurontin or gabapentin was one of them, correct?

A. Yes.

Q. We heard your interpretation of this, but now I want to ask you about what the FDA says.

So will you turn to the executive summary, page 5?

The overview. Do you have that?

Follow along with me, Doctor.

"The U.S. Food and Drug Administration (FDA) concerned about the potential for elevated risk of suicidality (suicidal behavior or ideation) from the use of antiepileptic drugs carried out a meta analysis of 11 drugs."

Is that what it says?

A. Yes.

Q. Let's drop down to findings. I just want to read this first sentence here. Follow along, Doctor.

"There are 199 placebo-controlled trials consisting of 27,863 patients in drug arms and 16,029 patients in placebo arms from 11 drugs that formed the primary analysis population."

That's what it says, right?

A. That's what it says.
Q. So they were taking all the drugs and all the trials and doing a meta analysis of that --
A. A pooled analysis.
Q. -- of that data?
A. A pooled analysis of all 11 drugs, yes.
Q. Let's turn to what the FDA concluded, which is page 6, lower right-hand corner.

You see the paragraph 1.3, "Conclusions"? You got that paragraph?

A. Yes, I do.
Q. Okay. And again, this is our FDA on May 23, 2008 issued this conclusion: "In conclusion, antiepileptic drugs are associated with increased risk of suicidality relative to placebo in randomized placebo-controlled trials. The effect appears consistent among the group of 11 drugs."

Isn't that what our FDA found in May 2008?

A. That's what they wrote.
Q. Thank you, Doctor. That's all I have.

THE COURT: Anything?

(Discussion off the record.)

MR. HOOPER: I think we're finished.

THE COURT: Thank you. Good, we've finished. See you tomorrow. If we're not all in an arc.

THE CLERK: All rise for the jury.

(Jury left the courtroom.)

(Discussion off the record.)

THE COURT: I do want this on the record.

(At sidebar on the record.)

THE COURT: I do want to come up with a protocol on how to get this to her.

So we need to get this woman a transcript of today's proceedings, but it will be incomprehensible unless she also has the chalks. So I thought what I might do is actually bring her in -- assuming she comes in tomorrow -- and hand her a packet, but I -- because she'll have two days to read it. But in general, of course, we don't have the chalks go back to the jury, so my theory would be is I have her hand them back to me Friday morning so that -- and ask her not to display the chalks to the jurors so that there's no undue emphasis on either side's argument.

It reminded me of the more general issue in that I'm not sure you've all been marking your chalks, and for the 1st Circuit, if it ever gets there -- or the Supreme Court, one would think that one should have a complete set of the chalks that each witness is relying on. So just marking them for identification, I think, both sides. And is it possible to at least talk about which witness they came in from? We haven't been doing this from the beginning, and I think that's my fault for not insisting on it.

Do you have a complete set of chalks?

MR. SOBOL: Yes.

THE COURT: And do you?

MS. ARMSTRONG: I'm sure we do. Most of it has been centralized.

THE COURT: Maybe we'll do that before the end of the trial, which is actually coming up.

So I got the -- we finished this witness, and I think we should probably just finish Glanzman tomorrow so we can officially rest here.

Although I've already received the memos, I'll expect your memos at least by Thursday at 5:00. Does that make sense?

MR. SOBOL: Thank you, your Honor.

THE COURT: And then we'll argue it on Friday afternoon, although I'm not sure I will have had time to read the plaintiff's by then. So we'll just go with that.

What about your next witnesses?

MR. CHEFFO: It's Dr. Brenner. We are probably, in light of scheduling and everything, I think we're going to need those depositions to use tomorrow. So we may only have Dr. Brenner tomorrow.

THE COURT: I prefer that than having that, because I can't call him back the next day. I think that's a great way to go.

MR. CHEFFO: We can even come back this afternoon -- I

don't know what your schedule is -- because we can then cut -- what we handed you today is, I think, about an hour and a half --

THE COURT: Have you conferred on the objections?

MR. CHEFFO: Well, we sent them, I think --

MR. SOBOL: No.

MR. CHEFFO: We sent them back and forth, but I think at this point --

THE COURT: How many are there? Are there hundreds?

MR. CHEFFO: Total, I think it's only about an hour and a half of testimony.

THE COURT: I don't know if I can -- I'm sorry, I'll try and do it this afternoon.

MR. CHEFFO: Whatever you can get through, your Honor, will help. But that will --

THE COURT: What does Brenner talk about?

MR. CHEFFO: Brenner is a pain --

THE COURT: A pain specialist.

MR. CHEFFO: Pain specialist.

MR. HOOPER: He's Harvard.

THE COURT: Can he consult here?

MR. CHEFFO: We have the perfect product for him.

MR. HOOPER: I have the solution for Mr. Sobol.

MR. CHEFFO: The only thing, on the record, I don't know what your Honor's view, notwithstanding the rulings

limiting Rothschild, I think they asked a number of questions which went well beyond and went -- I believe, went into various areas.

THE COURT: There was one I have to agree started merging there. I leaned over, and he stopped.

MR. CHEFFO: Even earlier he asked him about the Vieta and the study, he asked him about efficacy, and then he cut him off and said you weren't shown anything.

THE COURT: I cut him off.

MR. GREENE: I never asked about the other.

THE COURT: I cut him off in the one area I would completely agree with you we were moving that way.

In any event, good. See you tomorrow.

And just off the record.

(Discussion off the record.)

(Court adjourned at 1:10 p.m.)

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CERTIFICATION

We certify that the foregoing is a correct transcript of the record of proceedings in the above-entitled matter to the best of our skill and ability.

/s/Debra M. Joyce March 15, 2010
Debra M. Joyce, RMR, CRR Date
Official Court Reporter

/s/Lee A. Marzilli March 15, 2010
Lee A. Marzilli, RPR, CRR Date
Official Court Reporter